② No. 02 767 NOV 13 2002

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IN THE

Supreme Court of the United States

OCTOBER TERM, 2002

FAIRFAX NURSING HOME, INC.,
Petitioner

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Seventh Circuit

APPENDIX TO PETITION FOR WRIT OF CERTIORARI

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UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

300 F.3d 835; 2002 U.S. App. LEXIS 16505

FAIRFAX NURSING HOME, INCORPORATED, Petitioner,

v.

UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, Respondent.

No. 01-4088

May 29, 2002, Argued

August 15, 2002, Decided

PRIOR HISTORY: Petition for Review of a Final Decision of the Department of Health and Human Services Department Appeals Board, Appellate Division. DAB No. 1794.

DISPOSITION: **AFFIRMED**.

COUNSEL:

For FAIRFAX NURSING HOME, INCORPORATED, Petitioner: Brian E. Neuffer, WINSTON & STRAWN, Chicago, IL USA.

For UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, Respondent: Ted K. Yasuda, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Office of the General Counsel, Region V, Chicago, IL.

JUDGES: Before RIPPLE, DIANE P. WOOD and EVANS, Circuit Judges.

OPINION BY: RIPPLE, Circuit Judge.

Fairfax Nursing Home is a skilled nursing facility participating in Medicare and Medicaid. Fairfax was assessed a civil monetary penalty ("CMP") by the Center for Medicare and Medicaid Services ("CMS") because of its failure to comply substantially with Medicare regulations governing the care of respirator-dependent nursing home residents. Fairfax appealed to the Department Appeals Board of the Department of Health and Human Services ("HHS"); after a hearing before an Administrative Law Judge, both the ALJ and the Appellate Division affirmed the CMP. Pursuant to 42 U.S.C. §§ 1320a-7a(e) and 1395i-3(h)(2)(B)(2), Fairfax appeals that decision to this court. Fairfax argues that the Department Appeals Board ("DAB") erroneously placed the burden of proof on Fairfax and that the ALJ applied the incorrect legal standard in determining that Fairfax had violated HHS regulations. For the reasons set forth[**2] in the following opinion, we affirm the decision of the Appeals Board.

I. BACKGROUND

A. Facts

Fairfax is a skilled nursing facility ("SNF"), see 42 U.S.C. § 1395i-3(a); 42 C.F.R. § 488.301, participating in Medicare and Medicaid (collectively "Medicare") as a provider. Regulation of SNFs is committed to the Center for Medicare and Medicare Services, formerly known as the Health Care Financing Administration ("HCFA"),[1] and to state agencies with whom the Secretary of Health and

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[1] We shall refer to this agency by its present name, CMS, because it has been more than one year since the name change was implemented. See 66 Fed. Reg. 35,437 (July 5, 2001). However, in some places, when quoting from the record or the decisions of the ALJ and the Appellate Division, the agency is referred to as HCFA.

Human Services has contracted. See 42 U.S.C. § 1395aa(a). The primary method of regulation is by unannounced surveys of SNFs, conducted in this case by surveyors of the Illinois Department of Public Health ("IDPH"). See 42 U.S.C. § 1395i-3(g). These surveys are conducted at least once every 15 months. See *Id.* § 1395i-3(g)(2)(A)(3). If the state survey finds violations of Medicare regulations, the state may recommend penalties to CMS. The civil monetary penalty imposed here was based on an IDPH recommendation.

CMS imposed the penalty because of series of failures in Fairfax's care of ventilator-dependent residents. On December 20, 1996, R10, a ventilator-dependent resident at Fairfax, suffered respiratory distress and required emergency care.[2] Respiratory therapists administered oxygen directly to R10, and one therapist turned off R10's ventilator because the alarm was sounding. Once R10 was stabilized, the therapists left, but neglected to turn the ventilator back on. As a result, R10 died. Prompted by this incident, Fairfax began to develop a policy for the care of ventilator-dependent residents. That policy was completed in February 1997 and was implemented in early March of that year. The policy provided that once the resident was stabilized following an episode of respiratory distress: the nurse will check the resident & chart Q 15 minutes X 4 (for a total of 1 hr.) encompassing the following: vital signs/respiratory status oxygen stats [saturation] /lung sounds/vent settings /level of consciousness/ odor color and consistency of secretions & comfort level of the resident. Admin. R., App. A at 517.

On March 2, 1997, R126 was observed to have a low oxygen saturation level, an elevated pulse and temperature, and to be breathing rapidly. These signs indicated that the resident was having respiratory difficulties. R126's physician was called; he ordered a chest x-ray and gave several other instructions. However, contrary to Fairfax's policy, R126's medical chart did not reflect whether these orders were carried out. R126 died shortly thereafter.

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[2] All residents are denoted by number to respect their privacy.

On March 5, 1997, R127 was found with low oxygen saturation and mottled extremities. Fairfax staff failed to make a complete assessment, took no vital signs, made no follow-up assessments and did not notify a physician. On March 7, R127 was found cyanotic and required five minutes of ambu-bagging. Nurses charted four follow-up notes, but only observed R127's color and oxygen saturation and took no other vital signs. Also on March 7, during the 7 a.m. to 3 p.m. shift, three episodes of respiratory distress were noted, each of which required ambu-bagging. No physician was called. On March 10, R127's skin was observed turning blue, but there was no record of treatment for respiratory distress and no vital signs or assessments were charted. On March 21, R127 had another episode, this time with mottled legs, shaking and a dangerously low oxygen saturation. The physician was present; R127 was ambu-bagged and administered Valium. There was no complete assessment and no follow-up. On March 25, R127 was found to have a severe infection and died on March 27.

On March 23, 1997, R83 was found non-responsive with low oxygen saturation, low blood pressure, an elevated pulse rate and a low respiratory rate. R83 was ambu-bagged, and the treating physician was called. The first noted follow-up was an hour later and 2-1/2 hours passed before R83 was monitored again.

On April 2, 1997, a state surveyor observed a Fairfax employee fail to use sterile procedures while performing tracheostomy care on R6 and R11. The same employee also neglected to hyper-oxygenate the residents before or after suctioning the tracheostomy.[3]

On April 3, 1997, R68 became cyanotic, with low oxygen saturation, which required ambu-bagging and an increase in the amount of oxygen given through the ventilator. The records for R68 failed to note R68's vital signs, and the record did not reflect whether R68 oxygen saturation level ever returned to a normal level. On April 4, R68 was not sufficiently stable to permit a routine tracheostomy change.

After a survey on April 8, 1997, IDPH surveyors determined that Fairfax's actions and omissions posed "immediate jeopardy" to the health and safety of its residents. Specifically, Fairfax had violated 42 C.F.R. § 483.25(k), which pertains in part to the special care of ventilator-dependent residents. CMS concurred and notified Fairfax by a letter dated May 7, 1997, that CMS was imposing a CMP of $3,050 per day for a 105-day period, from December 20, 1996, through April 3, 1997, during which Fairfax was not in substantial compliance with HHS regulations governing the care of ventilator-dependent residents. CMS also assessed a penalty for a period of noncompliance running from April 4, 1997, through May 14, 1997. The total penalty for this latter period was $2,050, and Fairfax did not challenge it.

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[3] Hyper-oxygenation refers to "giving the patient or resident more air prior to suctioning, because when you introduce the suction catheter that's attached to the suction machine and you're actually drawing out both secretions and air, and when you hyper-oxygenate a patient or resident you're giving them air to . . . help them through the process." Admin. R., App. A at 294. This procedure should be followed both before and after suctioning. See *Id.* at 295.

B. Administrative Law Judge's Decision

Fairfax appealed the CMP to the HHS Department Appeals Board ("DAB"), which reviews the imposition of CMPs pursuant to a provider's right of review under 42 C.F.R. § 498.5. The DAB assigned the case to an administrative law judge who held a hearing in late May and early June 2000. Applying an earlier DAB Appellate Division decision, Hillman Rehabilitation Center v. United States, DAB No. 1611 (1997), the ALJ required that CMS make out a prima facie case for the imposition of the CMP, but assigned the ultimate burden of proof to Fairfax. Thus, Fairfax had to prove, by a preponderance of the evidence, that it was substantially compliant with the applicable regulations. The ALJ affirmed CMS' initial determination to impose a CMP of approximately $320,000 on Fairfax. In doing so, the ALJ found that a state of immediate jeopardy prevailed at Fairfax from December 20, 1996, until April 3, 1997, due to Fairfax's violations of 42 C.F.R. § 483.25(k).

The ALJ discussed each of the violations found by the state surveyors, beginning with the death of R10. R10 died, in part, the ALJ concluded, because Fairfax did not have in place a policy for the monitoring of ventilator-dependent residents following an episode of respiratory distress. This lack of a policy and later failures to comply with the new policy posed severe risk to the health and well-being of the patients. The ALJ found that all but one of the surveyors' reported violations constituted a risk to patients at the immediate jeopardy level. The ALJ emphasized the repeated monitoring failures and the threat those failures posed to the residents. The ALJ found that "there is not only a prima facie case of noncompliance here, but the preponderance of the evidence is that Petitioner was not complying substantially" with the regulations governing the proper care of vent-dependent residents.

Admin. R. at 24. Finally, the ALJ found that the amount of the CMP was reasonable.

C. Department Appeals Board, Appellate Division Decision

Fairfax appealed the ALJ's decision to the DAB Appellate Division. Fairfax argued that the ALJ erred following the Appellate Division's earlier ruling in Hillman and assigning the ultimate burden of proof to Fairfax. It further contended that the ALJ applied the wrong legal standard, linked together unrelated incidents and that the amount of the CMP was punitive, rather than remedial.

With respect to the burden of proof, CMS submitted that Fairfax had waived the issue by not raising it before the ALJ. The Appellate Division took note of this objection, but decided the issue on the merits. The Appellate Division first concluded that the burden of proof was irrelevant because the evidence was not in equipoise. The Appellate Division nevertheless reaffirmed Hillman and rejected Fairfax's argument. The Appellate Division also rejected Fairfax's other arguments, determining that the ALJ applied the proper legal standard, that the ALJ's decision was supported by substantial evidence and that the amount of the CMP was reasonable. Fairfax appeals. We have jurisdiction under 42 U.S.C. § 1395i-3(h)(2)(B)(2) and 42 U.S.C. § 1320a-7a(e).

II DISCUSSION

We must now determine whether substantial evidence supports CMS' conclusion that a state of immediate jeopardy prevailed at Fairfax from December 20, 1996, until April 4, 1997.[4]

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[4] In Hillman Rehabilitation Center v. United States, DAB No. 1611 (1997), available at 1997 WL 123708, the Appellate Division of the HHS Department Appeals Board held that in termination hearings

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before an ALJ, the sanctioned facility bears the burden of persuasion once HHS has made a prima facie showing to justify the CMP. See Hillman, at 1; Appellant's App. 1. This rule was extended to civil monetary penalty cases by Cross Creek Health Care Center v. HCFA, DAB No. 1665 (1998), available at 1998 WL 479291. Fairfax argues that the Hillman rule violates the Administrative Procedure Act in two ways.

HHS argues that Fairfax waived its objection to HHS' assignment of the burden of proof to Fairfax by failing to raise the issue before the ALJ. Fairfax did raise the issue on appeal to the DAB Appellate Division. Under the statute governing our review, a party must raise an issue before "the Secretary" in order to preserve the issue. See 42 U.S.C. § 1320a-7a(e). Nevertheless, we think raising the issue on appeal within the DAB is sufficient to preserve it for our review. Further, the Appellate Division itself did not rely on waiver and resolved the merits of Fairfax's appeal.

Fairfax submits that the Secretary was required to promulgate this rule by notice-and-comment rulemaking and that such a rule could not be adopted by adjudication. Second, Fairfax argues that Hillman violates APA § 7(c), which places the burden of proof on the "proponent of a rule or order." 5 U.S.C. § 556 (d).

We believe that several reasons militate against our addressing this issue at this time. First, the issue does not affect the outcome in this case. By its own terms, the rule in Hillman is operative only when the evidence is in equipoise, and, as our discussion in the text indicates, the evidence in this case certainly cannot be characterized as in equipoise. Secondly, we believe that this issue ought to be addressed with great prudence and caution. The Appellate Division has not addressed the application of this rule to civil monetary penalties in any comprehensive manner. Premature adjudication on our part will not be helpful in achieving accuracy or clarity in this important area of administrative practice. Definitive adjudication on our part is best reached after that administrative body has had the opportunity to set forth in more plenary fashion than it has in this case the justification for this rule.

A. We first address Fairfax's argument that the ALJ employed the incorrect legal standard. The regulations set up two basic categories of conduct for which CMPs may be imposed. *See* 42 C.F.R. §§ 488.408, 488.438. The upper range, permitting CMPs of $3,050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a resident or, under some circumstances, repeated deficiencies. *See Id.* § 488.438(a)(1)(i). By contrast, the lower range of CMPs, which begin at $50 per day and run to $3,000 per day, is reserved for "deficiencies that do not constitute immediate jeopardy, but either caused actual harm or have the potential for causing more than minimal harm." *See Id.* § 488.438(a)(2)(ii). "Immediate jeopardy" is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.* § 488.301.

Fairfax emphasizes the ALJ's use of the term "potential" to describe the probability of harm in several of the ALJ's findings. It submits that the ALJ's use of this terminology establishes that the deficiencies in question were deserving of "lower range" penalties. We take each in turn.

Finding 1(b): Petitioner failed to carry out the treating physician's orders and failed to properly document R126's medical charts. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy. Admin. R. at 8. Fairfax contends that potential for serious harm is insufficient to constitute immediate jeopardy, which requires that the provider's omission be likely to cause serious harm or death. However, in the discussion below this finding, the ALJ found that "Petitioner was woefully inadequate in the treatment and care of R126. . . . Such conduct caused or was likely to cause serious injury, harm, impairment or death to the resident." *Id.* at 9. The ALJ found that "the record presents a picture of a lackadaisical staff, rather than a staff aggressively treating a pneumonia that was further aggravating the resident's already compromised health." *Id.* at 10. The ALJ clearly was aware of the proper standard for immediate jeopardy and applied it correctly.

Finding 1(c) addressed Fairfax's failure to monitor R127 after R127's episodes of respiratory distress. The ALJ found that this monitoring failure "had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy." Admin. R. at 11. Fairfax argues that this is an indication of the ALJ's application of a lower standard than immediate jeopardy as defined in the regulations. Again, the ALJ's discussion of this finding demonstrates that he was well aware of the proper standard and applied it correctly. The ALJ devoted four pages of his opinion to discussing the treatment of R127, and addressed the specific risks posed to the resident by Fairfax's failure to monitor R127 after several respiratory episodes in close succession. He closes his analysis with a finding that the failures of the staff to assess properly and monitor the patient, as well as the failure to call the treating physician, "exposed the resident to risk of serious injury, harm, impairment, or death." *Id.* at 16.

The other findings of the ALJ that are questioned by Fairfax, when read in context, likewise make clear that the lapses were of a severe nature.

Finding 1(d) discussed Fairfax's failure to monitor R83 and R68, which "had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy." Admin. R. at 16.

In Finding 1(e), which addressed Fairfax's failure to ensure that R6 and R11 received proper tracheostomy care, the ALJ concluded that "this had the potential for serious injury, harm, impairment, or death to the residents and constitutes immediate jeopardy." *Id.* at 18. Fairfax again cites the ALJ's failure to use the precise terminology of 42 C.F.R. § 488.301 as evidence that he applied the wrong standard. Close attention to the body of the opinion, once again, reveals that the ALJ both understood the term's meaning and applied it correctly. In finding 1(c), the ALJ had already discussed the risks posed by Fairfax's failure to monitor residents following an episode of respiratory distress, so there was no need to repeat that discussion in finding 1(d), which dealt with the same issue. The ALJ's conclusion with respect to R83 makes manifestly clear that there was no misunderstanding of the applicable standard: "That R83 survived Petitioner's incompetent care and treatment does not excuse the fact that he was placed at risk of serious injury, harm, impairment, or death." Admin. R. at 17.

With respect to R68, the ALJ remarked in a similar vein: "Ms. Daniels testified that it was 'pretty lucky' that nothing serious happened to R68, because, in a matter of minutes, brain damage could be sustained from lack of oxygen. Petitioner's duty to provide appropriate respiratory care to its ventilator-dependent residents cannot be a matter of chance." *Id.* at 17-18 (citation omitted). Under finding 1(d), the ALJ did point out Fairfax's violation of its guidelines and its monitoring errors. The conclusion is inescapable that the monitoring failures described in finding 1(d) could lead to the same dire consequences the ALJ chronicled in finding 1(c). The same is true with respect to finding 1(e). In similar language, the ALJ concluded that patients R6 and R11 were "placed at serious risk of injury, harm, impairment or death" from the "deficient tracheostomy" care that they received. *Id.* at 20.

As the members of the Appellate Division noted, a fair reading of the ALJ's opinion also makes clear that he focused not simply on the situation of each individual patient, but also on the entire state of readiness in the facility during the time in question. Fairly read, his "bottom line" is that a respiratory patient in Fairfax during the time in question was in continuous jeopardy of serious injury or death because of the systemic incapacity of the facility to render the necessary care to sustain life and avoid serious injury. The record is replete with references to the danger of infection to vent-dependent residents living in nursing homes. The death of R10 was the beginning of a series of events that document all too graphically the finding of the ALJ.

Finally, we note that the ALJ carefully and correctly delineated the entire regulatory scheme before he embarked on his analysis of the individual situations of the patients. This manifestation of his understanding of the distinctions that he is now accused of misunderstanding and misapplying supports further the Appellate Division's estimation - and ours - that he both understood the law and properly applied it.

B. We also believe that the HHS' decision is supported by substantial evidence. The state surveyors documented numerous instances of Fairfax's failure to care adequately for its respirator-dependent residents. The common thread running through most of these omissions is Fairfax's repeated lack of follow-up and monitoring after a resident experienced respiratory distress. Beginning with the death of R10, and continuing throughout the period in question, Fairfax did not ensure that, once a resident had an episode, that resident was examined at regular intervals in the time immediately following the incident. The record firmly supports HHS' determination that a state of immediate jeopardy to resident health existed at Fairfax from December 20, 1996, until April 3, 1997.

Conclusion

The Board's decision was supported by substantial evidence and, therefore, it is affirmed.

AFFIRMED

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
APPELLATE DIVISION

No. A-2001-75

FAIRFAX NURSING HOME INC., PETITIONER
v.
HEALTH CARE FINANCING ADMINISTRATION, RESPONDENT

DAB No. 1794
2001 HHSDAB LEXIS 112

October 30, 2001

PANEL: Donald F. Garrett, Marc R. Hillson, Judith A. Ballard, Presiding Board Member

OPINION:

DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Fairfax Nursing Home, Inc. (Fairfax) appealed a March 22, 2001 decision by Administrative Law Judge (ALJ) Jose A. Anglada affirming a determination by the Health Care Financing Administration (HCFA)[5] to impose a civil money penalty against Fairfax. Fairfax Nursing Home, Inc., DAB CR753 (2001) (ALJ Decision). For the reasons stated below, we uphold the ALJ Decision. We affirm and adopt his findings of fact and conclusions of law.

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[1] **Although HCFA has been renamed the Centers for Medicare & Medicaid Services (CMS), we continue to use "HCFA" below since that acronym was used to refer to the agency at the time that the actions at issue here were taken and that the testimony discussed was given. See 66 Fed. Reg. 35,437 (July 5, 2001).**

Legal Background

Requirements for long-term care facilities that seek to participate in the Medicare program as a skilled nursing facility under section 1819 of the Social Security Act (Act), or in the Medicaid program as a nursing facility under section 1919 of the Act, are set out at 42 C.F.R. Part 483. The general "quality of care" requirement at section 483.25 provides that – Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. More specifically, subsection 483.25(k) provides that the facility "must ensure" that residents receive proper treatment and care for "special services," including tracheostomy care, tracheal suctioning, and respiratory care.

Compliance with these requirements is determined through the survey and certification process, set out at 42 C.F.R. Part 488, Subpart E. Surveys are generally conducted by a state survey agency under an agreement with HCFA (although HCFA may itself conduct surveys and revisits). Subpart F of Part 488 specifies the remedies that may be imposed by HCFA (or a state where appropriate) based on a finding that a facility is not in substantial compliance with the requirements. Factors that must be considered in selecting what remedy to impose include the seriousness of the deficiencies, including whether the deficiencies constitute immediate jeopardy, and whether the deficiencies are isolated, constitute a pattern, or are widespread. 42 C.F.R. 488.404. Other factors that may be considered include the relationship of one deficiency to other deficiencies. One of the available remedies is a civil money penalty (CMP). Section 488.430 provides that - HCFA . . . may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy. "Immediate jeopardy" is defined to mean - a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. 42 C.F.R. 488.301.

An upper range CMP, $3,050 to $10,000 per day, must be imposed for deficiencies constituting immediate jeopardy to the facility's residents. 42 C.F.R. §§ 488.408; 488.438(a)(1)(i). A per day penalty "may start accruing as early as the date that the facility was first out of compliance" and be computed for the "number of days of noncompliance until the facility achieves substantial compliance" or is terminated from the program. 42 C.F.R. §§ 488.440; 488.454.

A facility may appeal a certification of noncompliance leading to an enforcement remedy, but may not appeal the choice of remedy or the finding that deficiencies pose immediate jeopardy. 42 C.F.R. 488.408(g); 498.3(b)(12); 498.3(d)(10). A determination with respect to the level of noncompliance may be appealed only if a successful challenge on this issue would affect the range of CMP amounts that HCFA could collect. 42 C.F.R. §§ 498.3(b)(13); 498.3(d)(10); 488.438(e). HCFA's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. 498.60(c). This includes HCFA's finding of immediate jeopardy. Woodstock Care Center, DAB No. 1726, at 9, 38 (2000).

Under 42 C.F.R. Part 498 procedures, there is a right to request a hearing by an ALJ assigned to the Departmental Appeals Board and a right to request review of an ALJ decision by the Board itself. A request for review of an ALJ decision must specify the issues, the findings of fact or conclusions of law with the party disagrees, and the basis for contending that the findings and conclusions are incorrect. 42 C.F.R. 498.82(b).

HCFA's findings in this case were based on a survey performed by the Illinois Department of Public Health (IDPH), from April 1 through 8, 1997. HCFA determined to impose a penalty of $3050 per day for the 105-day period from December 20, 1996 through April 3, 1997, and a penalty of $50 per day for the period April 1 through May 14, 1997. Fairfax appealed the $3050 per day penalty (totaling $320,250), including the level of noncompliance, but did not appeal the remaining penalty (totaling $2,050). ALJ Decision at 2. HCFA's findings for the higher level penalty were based on alleged deficiencies in meeting the requirements of 42 C.F.R. 483.25(k) at the immediate jeopardy level, based on findings with respect to facility residents identified as R10, R126, R127, R83, R68, R6, R11, and R130.

The ALJ Decision

In his decision, the ALJ made the following numbered findings of fact and conclusions of law:

1. Petitioner was not in substantial compliance with federal participation requirements from December 20, 1996 through April 3, 1997.

   a. Petitioner failed to implement a policy concerning ventilator dependent residents, and, through its carelessness, brought about the premature demise of R10. This constitutes immediate jeopardy.

   b. Petitioner failed to carry out the treating physician's orders and failed to properly document R126's medical charts. This had the potential for serious injury, harm, impairment or death to the resident and constitutes immediate jeopardy.

c. Petitioner failed to adhere to the guidelines it had developed in February 1997, and implemented at the beginning of March 1997 for ventilator dependent residents in respiratory distress by not monitoring or providing proper follow-up assessments to R127. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy.

d. Petitioner failed to adhere to the guidelines it had adopted in March 1997 for ventilator dependent residents in respiratory distress by not monitoring or providing proper follow-up assessments to R83 & R68. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy.

e. Petitioner failed to ensure that R6 and R11 received proper tracheostomy care. This had the potential for serious injury, harm, impairment, or death to the residents and constitutes immediate jeopardy.

f. The conduct of Petitioner with respect to R130 does not constitute a deficiency.

2. Beginning December 20, 1996 and continuing through April 3, 1997, Petitioner failed to comply with requirements of 42 C.F.R. 483.25 at the immediate jeopardy level.

3. The amount of the penalty imposed by HCFA is reasonable. Under each of his major findings and conclusions, the ALJ set out the survey findings, and then

discussed his findings based on the evidence presented, stating which witnesses he found credible and why he rejected Fairfax's arguments. We do not here repeat the detailed findings from the ALJ Decision, except to the extent necessary to address Fairfax's arguments on appeal.

Standard for Review

Under the guidelines for Board review under 42 C.F.R. Part 498, the standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record as a whole. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. See e.g., *Woodstock Care Center*, DAB No. 1726, at 8-9 (2000).

Issues on Appeal

On appeal, Fairfax raised a threshold issue regarding whether the ALJ applied the appropriate burden of proof. Fairfax also alleged generally that the ALJ erred by - using the wrong legal standard for deciding whether a deficiency existed at all, substituting the facility's new respiratory care protocol (adopted after the death of R10) for the applicable standard of care; 1 concluding that the mere "potential" or "risk" of harm is sufficient to warrant a finding of immediate jeopardy; 1 linking unrelated incidents (alleged deficiencies occurring during the last 30 days of the 105-day period) to the deficiency that resulted in R10's accidental death on December 20, 1996, and assuming an unbroken period of immediate jeopardy during the intervening time; and 1 affirming a total penalty that is improperly punitive, rather than remedial.

While not alleging that any of the ALJ's specific findings of fact were not supported by substantial evidence in the record, Fairfax set out its version of the facts with respect to each of the residents for which findings were made. Fairfax asserted, based on its version of the facts, that the "alleged deficiencies re R126, R127, R83, R68, R6, & R11 do not rise to the level of immediate jeopardy." Fairfax Appeal Brief (App. Br.) at 19-24.[6]

Below, we first discuss the threshold issue regarding burden of proof. We then address each of the general allegations of error, discussing as necessary the more detailed arguments made related to each of the allegations. Finally, we state why we conclude that the ALJ's factual findings are supported by substantial evidence in the record and reject Fairfax's characterization of the incidents in question.

1. The ALJ applied the appropriate burden of proof.

In *Hillman Rehabilitation Center*, DAB No. 1611 (1997), this Board reversed an ALJ decision that had placed the ultimate burden of persuasion on HCFA to establish that a rehabilitation agency that had previously entered into a Medicare provider agreement no longer met the conditions for participation, and therefore could be terminated from the program. Based on the relevant

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[2] Fairfax also objected to the change of administrative law judges that occurred prior to the hearing in this case. Fairfax provided an affidavit attesting that the first judge had told counsel that if IDPH "had conducted an investigation on January 2, 1997 to investigate the incident of December 20, 1996, he would rule that Immediate Jeopardy could not be imposed on Fairfax from December 20, 1996 through April 3, 1997." Exhibit (Ex.) C. Fairfax asserted that the "unilateral reassignment of judges by HCFA" was a violation of due process. Id. at 28. We agree with HCFA that Fairfax did not timely raise this procedural issue. We note, however, that HCFA has no control over assignment of Departmental Appeals Board (DAB) judges. The DAB is independent of HCFA and assigns or reassigns cases to judges based on their availability to hear and decide cases.

statutory and regulatory language, prior administrative and court decisions, and the underlying purpose of protecting Medicare beneficiaries, this Board rejected the ALJ's rationale for placing the burden on HCFA. The Board concluded that the procedural concerns expressed by the ALJ could be addressed in a manner more consistent with the relevant provisions and underlying purpose. The Board held the following:

> FFCL 1A. HCFA must set forth the basis for its determination terminating a provider with sufficient specificity for the provider to respond, including the basis for any finding that a condition-level deficiency exists. The provider must then identify which of the findings material to the determination the provider disputes, and must also identify any additional facts the provider is asserting.
>
> FFCL 1B. At the hearing, HCFA has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case that HCFA had a legally sufficient basis for termination.
>
> FFCL 1C. At the hearing, the provider has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.
>
> FFCL 1D. The provider bears the ultimate burden of persuasion. To prevail, the provider must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with the relevant statutory and regulatory provisions. *Hillman* at 8; see also *Hillman* at 9-10.

The Board decision was upheld in *Hillman Rehabilitation Center v. United States*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). Subsequently, this Board determined in Cross Creek Health Care Center, DAB No. 1665, at 13, n.10 (1998),that the rationale in *Hillman* applies in the context of CMPs imposed on long-term care facilities.

Fairfax did not raise the issue of burden of proof before the ALJ. On appeal, however, Fairfax argued that placing the burden of proof on Fairfax was unconstitutional because it denied Fairfax due process. Fairfax also argued that the decision in *Hillman* constituted a substantive change in policy that the federal Administrative Procedure Act (APA) required to be promulgated through notice and comment rulemaking. In response to HCFA's argument that Fairfax had waived this issue by not raising it before the ALJ, Fairfax argued that its failure to raise the issue below should not be considered a waiver since an ALJ does not have the authority to invalidate a statute or regulation on constitutional grounds.

We first note that Fairfax misconstrues the nature of the *Hillman* decision. The applicable procedural regulations in 42 C.F.R. Part 498 are silent on burden of proof. The Board's decision in *Hillman* is thus in the nature of an order which, while establishing precedent for the ALJs hearing these cases, is not a "rule" under the APA. Moreover, the Board's decision in *Hillman* was consistent with prior decisions on burden of proof issued by the Social Security Administration Appeals Council, the Board's predecessor for reviewing ALJ decisions in these cases. Thus, it did not represent any change in policy. If the Board were persuaded that our determination on the burden of proof was unconstitutional, nothing in the applicable statutes or regulations would preclude us from reaching a different conclusion in this case. In any event, however, there is no merit to Fairfax's challenge to the ALJ Decision here based on its assertions about the burden of proof, for the following reasons:

As we explained in *Hillman*, which party has the ultimate burden of persuasion becomes significant only if the weight of the evidence is in equipoise. That is not the situation here. Fairfax's constitutional argument lacks merit. Fairfax presented no citations to relevant case law to support the proposition that a Medicare provider has a due process right to have the ultimate burden of persuasion placed on HCFA. For the reasons explained in *Hillman*, at pages 20-22, and affirmed on appeal, we conclude that there is no such right.

2. The ALJ did not improperly substitute Fairfax's protocol for the applicable standard of care.

After the death of R10, Fairfax developed a new protocol for care of ventilator dependent residents in respiratory distress. Fairfax alleged that the ALJ erred by applying this protocol as a substitute for the applicable standard of care. According to Fairfax, use of the new protocol against Fairfax is contrary to public policy, as evidenced in Federal Rule of Evidence No. 407. That rule provides:

> When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measure is not admissible to prove negligence or culpable conduct in connection with the event. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

Underlying this rule is the notion that use of corrective actions as evidence of negligence or culpable conduct could act as a disincentive to such measures and therefore jeopardize public health and safety. Fairfax also pointed to this Board's decision in *Lake City Extended Care Center*, DAB No. 1658 (1998) for the proposition that failure to follow an internal protocol is not necessarily evidence of a failure to adhere to the standard of care. Fairfax App. Br. at 18-19.

We first note that this is not a question about the admissibility of evidence. Fairfax did not timely object to the ALJ admitting its protocol into the record. Indeed, Fairfax submitted the protocol as its Exhibit 10. Moreover, evidence that is inadmissible under the Federal Rules of Evidence may be received in a Part 498 proceeding. 42 C.F.R. 498.61. The public policy underlying Rule 407 is inapplicable as well. The survey and certification regulations require corrective action for all deficiencies except isolated deficiencies with a potential for only minimal harm and no actual harm. 42 C.F.R. 488.408(f). Thus, admitting evidence of what corrective actions facilities took would not have the unintended consequence of discouraging them from taking such actions. HCFA pointed out, and Fairfax did not deny, that an exception to Rule 407 is recognized where remedial action is mandated by superior governmental authority. HCFA App. Br. at 56, citing 2 Weinstein's Federal Evidence 407.05[3], p. 407-27 (2nd Ed. 2001).

Fairfax's substantive argument that the ALJ erroneously substituted Fairfax's policy for the applicable standard of care also lacks merit. Fairfax's assertions about the policy ignore not only statements in the ALJ Decision, but also testimony from Fairfax's own witnesses with nursing credentials confirming the testimony of HCFA's witnesses with like credentials. The ALJ Decision noted that the purpose of the protocol, called "Nursing Guidelines for Ventilator Dependent Residents in Respiratory Distress," was to ensure not only proper care and treatment of such residents, but also to provide monitoring of such patients. He further noted that Fairfax's own Director of Nursing (DON) had testified that the protocol "embodied good nursing practices," that R10 should have been monitored after apparently having been stabilized, and that such monitoring is good nursing practice that "should be done on every resident that goes into any type of distress." ALJ Decision at 7, quoting Tr. at 502. The DON also testified about the development of the policy and the accompanying charting form, based on textbooks and respiratory certification for nurses; she indicated that it was good nursing practice before being put into writing and that the form "was developed to make everyone more in tune with what needed to be embodied in the charting." Tr. at 505-507. The surveyor, who was an experienced nurse, also testified that the monitoring required by the protocol is standard nursing practice in the area. Tr. at 141 (Daniels); see also Tr. at 152-154 (Daniels); 394 (Lawrence); 420-21 (Casares).

Fairfax presented no convincing evidence that its policy did not represent the applicable standard of care. Fairfax presented some testimony to the effect that the requirement in the protocol to monitor the patient by charting the vital signs and other observations might not always apply if the nurse did "little things" that stabilized the resident or if the initial intervention worked because the problem was a mechanical one such as a kink in the ventilator tubing. See, e.g., Tr. at 349 (Lawrence); Tr. at 492, 509 (Benda). The ALJ could, however, properly discount this testimony in light of the facts that no qualification appears on the face of the written policy (which Fairfax's witnesses in effect admitted represented the standard of care) and that the policy applied to "any resident in distress." P. Ex. 10; Tr. at 502 (Benda). Moreover, even if the ALJ had credited this testimony, it would not be sufficient by itself to undercut the ALJ's findings with respect to the particular residents at issue here. Substantial evidence in the medical records of the residents to whom the ALJ applied this protocol as the standard of care, as well as in the testimony as a whole, supports his findings that the residents were in respiratory distress that required monitoring to ensure that they had in fact been stabilized.

In light of the testimony establishing the protocol as the standard of nursing care, the ALJ did not err by disregarding the opinion of a physician witness (Dr. Saltiel) that suggested, contrary to the protocol, that physician contact was not necessarily required in circumstances of repeated episodes of respiratory distress. Moreover, the ALJ found Dr. Saltiel's testimony not credible regarding the protocol because he was confused about it and his testimony was contradicted. ALJ Decision at 13-14.

Fairfax's reliance on *Lake City* is misplaced. In that case, the ALJ had concluded that the fact that Lake City's protocol directed staff to call a physician if a resident's temperature exceeded 101 degrees gave rise to a presumption that this was the standard of care, but that the facility had rebutted the presumption by presenting persuasive evidence that this was not required. In this context, the Board adopted the ALJ's conclusion that "failure by a facility to comply with a protocol is not a failure to comply with a participation requirement where the protocol does not comport with a professionally recognized standard of care and where the participation requirement does not direct a facility to follow each of its internal protocols." *Lake City* at 18. Fairfax, however, presented no evidence here to rebut the presumption that the protocol it adopted reflected the professionally recognized standard of care. Moreover, as discussed below, the deficiency found by HCFA (and the ALJ) here was Fairfax's failure to have a guideline/procedure/protocol on respiratory care (whether written or otherwise) that was effectively communicated to staff and applied by them in the care of the residents. Fairfax did not deny that it needed to do this in order to ensure that residents receive the special services they need, as required by 42 C.F.R. 483.25(k).[7] Thus, we conclude that the ALJ did not err as alleged by Fairfax. The ALJ found that the policy merely articulated the applicable standard of care, and ample evidence in the record supports this finding.

3. The ALJ applied the correct legal standard and did not misapply the definition of "immediate jeopardy".

As mentioned above, "immediate jeopardy" means - a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. 42 C.F.R. 488.301. Fairfax argued that the ALJ departed from this definition, by concluding that mere

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[3] We do not here adopt HCFA's position that the State Operations Manual (SOM) interprets section 483.25(k) as incorporating a facility's internal policies by reference into the regulation. HCFA relied on a SOM section that merely directs surveyors to determine whether facility staff is following the facility's own protocol and/or written procedures for ventilators. HCFA Br. at 52, quoting SOM Appendix P at PP-112. HCFA cannot reasonably rely on this as a basis for applying an internal policy as though it had been incorporated by reference into the regulation, especially in light of the outcome-oriented approach in the long-term care requirements and Federal Register requirements for incorporation by reference. We also note that the decisions on which HCFA relied for the proposition that we must uphold any HCFA interpretation are inapposite to Part 498 cases, in which the Board renders the final decision on behalf of the Department.

"potential" or "risk" of harm was sufficient for immediate jeopardy, and therefore employed the wrong legal standard. Fairfax pointed to language in the ALJ's numbered findings, stating that deficiencies had the "potential" for harm (FFCLs 1.b., 1.c., 1.d., and 1.e.), and to statements in his discussion referring to "risk" of harm. In response, HCFA pointed to language in the ALJ Decision which HCFA said showed that the ALJ clearly understood the definition of "immediate jeopardy" and was applying it. HCFA cited certain court cases to support its position that the substance of the decision, rather than the wording, should control. Fairfax replied that "the ALJ failed to specifically find that the deficiencies related to FFCLs 1(b)-(e) were 'likely to cause' serious injury, harm, impairment or death" and that "the immediate jeopardy ruling for those findings, therefore, should be overturned." Fairfax Reply Br. at 2. Fairfax sought to distinguish the cases relied on by HCFA, arguing that, in this case, the problem is not merely a passing remark of the ALJ's or the sketchiness of the written opinion. Instead, Fairfax asserted, "Almost all of the ALJ's actual findings misstate the governing legal standard. The opinion is unambiguous on this point." *Id.* at 3 (emphasis in original).

We first note that the initial situation leading to HCFA's finding that Fairfax failed to comply with the requirement at 42 C.F.R. 483.25(k) to ensure that residents receive special services such as respiratory care was with respect to R10. With respect to this resident, the ALJ found the following in FFCL 1.a.: Petitioner failed to implement a policy concerning ventilator dependent residents, and, through its carelessness, brought about the premature demise of R10. This constitutes immediate jeopardy. ALJ Decision at 6. As Fairfax's argument seems to recognize, this finding is consistent with the definition of immediate jeopardy. In discussing this resident, the ALJ first stated that, in essence, the state surveyors had found that the staff caring for R10 "did not follow guidelines/procedures/protocols in the provision of respiratory care, and that lack of adherence directly caused the death of R10." Id. He then went on to discuss the evidence, concluding: It is unequivocal, from the facts of this case, that Petitioner's carelessness was the direct cause of R10's death. Tr. at 489. The lack of due care is first evident from the act of turning the resident's ventilator off, and then from not monitoring the resident after she apparently had been stabilized. . . . Furthermore, Petitioner did not have a written policy for the protection of ventilator dependent residents in respiratory distress. It is evident that whatever non-written guidelines existed were either improperly communicated to the attending staff or were not diligently applied. ALJ Decision at 8.

Second, the ALJ's FFCLs 1.b. to 1.e., to which Fairfax objected, not only refer to "potential" for harm, but also specifically state that each deficiency "constitutes immediate jeopardy." This at the very least undercuts Fairfax's contention that the specific findings are "unambiguous" and makes reference to the decision as a whole perfectly appropriate, as HCFA contended. An examination of the ALJ Decision as a whole indicates that the ALJ was aware of the definition of "immediate jeopardy" and intended to find that these situations were deficiencies with a likelihood of causing serious harm. Moreover, while Fairfax is correct that mere potential or risk is insufficient to meet the definition of immediate jeopardy, the terms "potential" and "risk" are not inherently inconsistent with the concept of "likelihood" in that definition. See *Woodstock Care Center*, DAB No. 1726, at 38 (2000). The issue is whether the "potential" or "risk" are sufficiently great to constitute a "likelihood." The ALJ's statements that the deficiencies constituted immediate jeopardy imply that he thought the potential/risk did rise to a likelihood.

Moreover, a finding of immediate jeopardy is not contingent on a finding that each individual incident placed a resident at such a degree of potential or risk of serious harm that there was a likelihood of harm to that specific resident at that particular time. The more incidents with a potential for serious harm, the more likelihood there is that such harm will occur to some similarly situated resident, particularly when, as in this case, the incidents evidence a failure to have and consistently follow protocols to avoid the potential harm. Findings about incidents related to individual residents are not themselves the deficiencies that must be corrected - the deficiency is the underlying failure to meet a participation requirement evidenced by the incident. 42 C.F.R. 488.301.

Fairfax's other general arguments related to the immediate jeopardy determination similarly lack merit, for the following reasons: [1] Contrary to what Fairfax implied in describing the incidents here, the mere fact that actual harm did not occur to each of the residents is irrelevant. Immediate jeopardy encompasses situations where there is a likelihood of serious harm. [2]Fairfax's reliance on a decision by a state ALJ reaching a somewhat different result is misplaced. The state ALJ did not have the same evidence before her, nor was she applying the same standards. See Fairfax Ex. B. Fairfax's arguments, however, raise the issue of what is the "legal standard" that a federal ALJ must apply in order to uphold a CMP at the immediate jeopardy level. As noted above, the regulations specifically state that HCFA's finding that a deficiency is at the immediate jeopardy level must be upheld unless "clearly erroneous." 42 C.F.R. 498.60(c).[8] The ALJ

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[4] This standard was explained in the preamble to this regulation as follows: "Survey team members and their supervisors ought to have

recognized this as the standard, concluding that -- Petitioner failed to show that HCFA's determination of immediate jeopardy was clearly erroneous. In fact, the preponderance of the evidence establishes the Petitioner's deficiency was at the immediate jeopardy level. . . . Petitioner did not prove by the preponderance of the evidence that it had eliminated the immediate jeopardy to its residents on any date prior to April 4, 1997. ALJ Decision at 24. He based this on 1) the evidence discussed under his second major conclusion, including testimony by the surveyor that "after R10's demise, the lack of the facility's immediacy in initiating a protocol to prevent any further problems placed residents at severe risk for harm, if not death," 2) the evidence supporting his findings related to other residents, and 3) his finding that "it was not until April 4, 1997, that Petitioner initiated a comprehensive plan to address and abate the immediate jeopardy." ALJ Decision at 23-24.

4. The ALJ did not err in determining the duration of the penalty.

Fairfax argued: "Even if the record could sustain an immediate jeopardy finding for one or more deficiencies, it does not support a finding of 105 days of continuous immediate jeopardy." Fairfax App. Br. at 22. Fairfax referred to the incident with R10 as "an isolated tragedy" and likened it to the situation in Hermina Traeye Memorial Nursing Home, CR756 (2001). In that case, the ALJ concluded that "a single isolated episode of staff error in the remote past" was not "persuasive evidence of an ongoing failure to comply . . . at a survey that takes place six months after the occurrence of the episode." Fairfax

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some degree of flexibility and deference in applying their expertise in working with these less than perfectly precise concepts." 59 Fed. Reg. 56,116; 56,179 (Nov. 10, 1994).

App. Br. at 23, quoting Hermina Traeye, CR756, at 18-19. According to Fairfax, the evidence regarding the event of December 20, 1996 related to R10 "does not support an inference that a general state of immediate jeopardy existed over the next 70 days," and, instead, the IDPH surveyor who visited Fairfax on January 2, 1997 "found no deficiencies." Fairfax App. Br. at 23. If immediate jeopardy had existed at that time, Fairfax asserted, the surveyor was required under HCFA policy to take immediate steps to protect the residents. Fairfax App. Br. at 23-24, citing State Operations Manual, §§ 7307, 7308, and 7309. According to Fairfax, HCFA failed to make a prima facie case that Fairfax's residents were in a continuous state of immediate jeopardy for 105 days." *Id.* at 22.

These arguments have no merit. First, Fairfax's attempt to characterize the events regarding R10 as an "isolated event" simply is not supported by the record before us. HCFA's finding of a deficiency constituting immediate jeopardy was based on Fairfax's failure to have policies/guidelines/protocols that were communicated effectively to staff. Fairfax did assert that it had a protocol that prohibited unplugging a ventilator during an episode of respiratory distress such as that experienced by R10, but did not assert that it had any written or oral policy/guideline/protocol at the time of the incident regarding monitoring a ventilator dependent resident following respiratory distress. HCFA's further finding that the immediate jeopardy was not abated until April 4 was based on Fairfax's admitted failure to put such a protocol in place prior to March 1997, and its failure thereafter to effectively communicate to staff the need to follow protocols on special services such as respiratory care, tracheostomy, and tracheal suctioning. This failure was evidenced by numerous incidents (up to and including the time of the survey) for which records showed a failure to follow protocols, particularly the protocol for residents suffering respiratory distress. The incidents were related in this respect. Contrary to what Fairfax asserted, the survey did not start on April 8, 1997. Rather, the record shows it started on April 1 and was completed on April 8. HCFA Exs. 1-6. The comprehensive steps that Fairfax took were after the surveyors had informed Fairfax that the state of immediate jeopardy might be found. HCFA Ex. 1, at 24. Thus, this case is distinguishable from the facts found by the ALJ in Hermina Traeye, where he found that HCFA was basing its finding that the immediate jeopardy continued solely on an inference from one episode.

Second, Fairfax also misrepresents what the record shows about the IDPH surveyor who visited the facility after R10's death. There is no evidence in the record that this surveyor ever found or informed Fairfax that it had "no deficiencies." Fairfax's DON testified that the surveyor said she made "no findings," but this is not the same as a finding of "no deficiencies." Tr. at 490 (Benda). Moreover Fairfax's administrator, whose testimony was more internally consistent, testified that, while the surveyor made a remark that turning off the ventilator for R10 appeared to be a "terrible mistake," she further indicated that her investigation of the incident was not yet completed. Tr. at 621-623 (Considine); compare Tr. at 503-504 (Benda). Indeed, there is evidence that the surveyor was still seeking information from the facility as late as March 24, 1997. Tr. at 680; P. Ex. 6. Moreover, it appears that her visit was merely an investigation, rather than a survey. There is no evidence in the record about when or whether this surveyor actually completed her investigation. Since it is not clear that she would have ever been obliged under the regulation to take the steps required when immediate jeopardy is found during a survey, it is not reasonable to infer from her failure to take those steps that she found no immediate jeopardy. Moreover, even if her investigation had been a survey resulting in a surveyor's finding that Fairfax was in substantial compliance, Fairfax could not rely on that finding. Under the regulations, surveyors make only recommendations with respect to compliance of Medicare facilities -- HCFA is not bound by those recommendations. 42 C.F.R. §§ 488.12, 488.330.

Fairfax is also mistaken in implying that it was entitled to prospective notice of a finding of noncompliance before a CMP may be imposed. The regulation at 42 C.F.R. 488.454 makes clear that HCFA may impose a CMP based on a finding of a noncompliance occurring between surveys and that the duration of such a CMP is until the facility "achieves substantial compliance." Generally, this point is determined by a revisit or by submission by the facility of written, credible evidence that HCFA finds acceptable to verify that corrections have been made. HCFA here reduced the amount of the CMP at the point where it determined Fairfax had abated the immediate jeopardy, while the surveyors were on site performing the survey.

The fact that HCFA did not make findings about the care provided to specific residents during the first 70 days after R10's death is irrelevant. Fairfax witnesses admitted that in that period Fairfax had not taken even the minimal corrective step of putting in place its new protocol. Fairfax, moreover, did not present any credible evidence that it had taken other corrective action sufficient to ensure that it was meeting the applicable standard of care during this 70-day period. See ALJ Decision at 22-23. While Fairfax presented evidence that it did do some in-service training, other evidence indicates that the training focused on matters other than monitoring residents following an episode of respiratory distress and was not effective. See, e.g., P. Exs. 8, 10; Tr. at 488, 544-545. Thus, HCFA could reasonably conclude that the immediate jeopardy situation persisted throughout this period, particularly in light of what later records showed about Fairfax's failure to in fact provide the appropriate care to residents suffering from respiratory distress, despite adoption in March of a protocol based on the standard of care. In sum, HCFA was not clearly erroneous in concluding that steps taken prior to April 4 were insufficient to abate the immediate jeopardy.

5. The ALJ did not impose a CMP that is punitive.

Fairfax argued that the CMPs recommended by HCFA and adopted by the ALJ are fatally flawed because they are punitive in nature, rather than remedial. Fairfax asserted that this rendered the CMPs contrary to the Constitution, the Medicare Act, and this Board's prior decisions. In support, Fairfax cited this Board's decision in *CarePlex of Silver Spring*, DAB No. 1627 (1997) and the ALJ decision on remand in *CarePlex of Silver Spring*, CR536 (1998). Fairfax App. Br. at 25. According to Fairfax, HCFA "admitted that the immediate jeopardy had ceased to exist a few days before the April 8 survey" and both parties "agreed that the alleged immediate jeopardy was abated because Fairfax had drafted and implemented its protocol for respiratory care prior to the date of the survey" prior to "any finding or hint from HCFA that a deficiency existed or that CMPs were accruing." Fairfax App. Br. at 27. Therefore, Fairfax asserted, "HCFA may not feasiblely argue that its recommended CMP served the necessary remedial purpose of 'induc[ing] the deficient facility to correct outstanding deficiencies promptly and effectively'," as required by the Board's decision in *CarePlex*.

Again, Fairfax's argument is predicated upon a misstatement of the facts. HCFA did not in fact admit that the immediate jeopardy was abated prior to the survey, nor agree that Fairfax had implemented its new protocol satisfactorily prior to the survey. The record shows that the survey in fact started on April 1 and that it was only after the surveyors had informed Fairfax that they considered immediate jeopardy to exist that Fairfax developed the comprehensive plan (outlined in the ALJ Decision) that HCFA found satisfactory to abate the immediate jeopardy. HCFA Ex 1. HCFA and the ALJ specifically found that the steps taken previously were inadequate. Substantial evidence in the record supports this finding, including the medical records for residents R126, R127, R83, R68, R6, and R11. The medical records show that the facility staff was not consistently following protocols Fairfax had developed, based on applicable standards of care, for providing special services such as respiratory care to residents.

As noted above, the regulations specifically permit imposition of CMPs for periods of past noncompliance since the last standard survey. This does not render the CMP punitive in nature. The threat of imposing the CMP led Fairfax to comply in this instance and the CMP will be an incentive in the future for Fairfax to maintain compliance. While some remedies may provide an incentive to correct existing deficiencies, the purpose is not so limited. As explained in the preamble to the 1994 regulations implementing sections 1819 and 1919 of the Act, Congress wanted to "discourage facility noncompliance that the Congress believed to be widely evident between surveys and thereby, to encourage lasting compliance." 59 Fed. Reg. 56,116; 56,175 (Nov. 10, 1994). The preamble further explained that Congress authorized imposing a CMP for past noncompliance, even if subsequently corrected, to create a "financial incentive for facilities to maintain compliance." 59 Fed. Reg. at 56,206, quoting H.R. Rep. No. 391, 100th Cong., 1st Sess. 473-6 (1987).

The suggestion by Fairfax that only if it knows in advance that a penalty will be imposed does it have sufficient notice that it should take steps to correct a deficiency is disingenuous. Even if HCFA had not yet made a noncompliance finding, the record shows that Fairfax clearly knew after the death of R10 that at the very least it needed to improve its care of residents experiencing respiratory distress by developing and implementing a protocol. Fairfax should have known, moreover, that adopting the protocol, but not taking sufficient steps to ensure it would be followed, would be inadequate to meet the regulatory requirement that it ensure that residents attain and maintain the highest practicable physical well-being, including by ensuring that residents receive special services, in accordance with their plans of care. In proposing this requirement, HCFA explained that it deliberately chose the word "ensure" with respect to treatment and care that the facility is responsible for providing "since this is the reason for the residents stay in the facility, as well as for program payment." 56 Fed. Reg. 48,826; 48,850 (Sept. 26, 1991). We also note that the amount of the penalty imposed is the lowest amount under the regulations that could be imposed on a per day basis for an immediate jeopardy level of noncompliance. Thus, having concluded that HCFA was not clearly erroneous in determining that immediate jeopardy existed during the period from December 20, 1996 through April 3, 1997, we do not have the authority to reduce the amount of the penalty.

6. The ALJ's findings regarding individual residents are supported by substantial evidence in the record as a whole.

As noted above, Fairfax did not take specific exception to the ALJ's factual findings made in his discussion of individual residents (as opposed to his general numbered conclusions). Instead, Fairfax argued generally that the incidents related to individual residents did not show immediate jeopardy and presented its version of the incidents, which differs in some respects from the ALJ's findings or which emphasizes different facts. We have addressed Fairfax's general arguments about immediate jeopardy above. We have reviewed the entire record and also conclude generally that the ALJ's findings are supported by substantial evidence. Below, we address the more specific arguments based on or implicit in Fairfax's version of the facts.

a. Substantial evidence in the record supports the ALJ's findings with respect to R10, and the facts emphasized by Fairfax are irrelevant.

Throughout its briefing, Fairfax characterized the death of R10 as an "accident" or an "isolated event" due to the failure of a respiratory therapist to follow Fairfax policy that a ventilator never be unplugged. Fairfax ignored the findings regarding its failure to have and to communicate to staff a protocol for monitoring ventilator dependent residents after an episode of respiratory distress to ensure that the resident is in fact stabilized and to evaluate the underlying cause of the distress. The ALJ found that this failure was a cause of R10's death since monitoring every 15 minutes for the first hour after the episode, per the protocol later adopted, would have revealed that R10's ventilator had been unplugged. Instead of directly challenging this finding, Fairfax presented a version of the events emphasizing that one of the respiratory therapists was with R10 until approximately 15 minutes before a nurse entered the room and found R10 dead at 1:15. The flaw in this approach is that the protocol (based on the standard of care) required nursing care to monitor the resident, so the presence of the respiratory therapist in the room is irrelevant. Indeed, the protocol is titled "Nursing

Guidelines . . . ." P. Ex. 10. The record shows that the last nurse who was present left the room at approximately 12:50, about 25 minutes before any nurse returned. HCFA Ex. 12, at 8.[9] The record also shows that, when the nurse did return at about 1:15, the purpose was to change R10's gastric feeding tube, rather than to monitor R10 to ensure that she had stabilized. *Id.* By then it was too late to revive R10. The fact that the police who investigated R10's death determined it was an "accident" is also irrelevant. As HCFA pointed out, a conclusion that there was no criminal intent in the unplugging of R10's ventilator is not tantamount to a finding that Fairfax was not deficient in its care of R10. Similarly, while the fact that the respiratory therapist who unplugged the ventilator had 20 years' experience may be relevant to show that Fairfax could have expected that he would know to never unplug a ventilator, it does not excuse Fairfax's deficiency in providing nursing care to R10.

b. Substantial evidence in the record supports the ALJ's findings about R126.

The ALJ thoroughly discussed the evidence and arguments regarding R126, finding that Fairfax failed to carry out the treating physician's orders, given after an episode of respiratory distress, and that R126's medical records fail to show that Fairfax took steps to increase his oxygen level, which was dangerously low. ALJ Decision at 8-11. The ALJ concluded that Fairfax was "woefully inadequate in its treatment and care of R126, in violation of 42 C.F.R. 483.25(k)" and that such conduct "caused or was

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[5] During the approximately 45 minutes between the onset of the respiratory distress at 12:30 and the time the nurse returned, no vital signs were charted. HCFA Ex. 1, at 20; P. Ex. 7. The surveyor testified that such monitoring was even more critical for R10 because she had been given Ativan, which would make her appear calm, even if she had not been stabilized. Tr. at 146.

likely to cause serious [*41] injury, harm, impairment or death to the resident." Id. at 9.

On appeal, Fairfax argued as it had before the ALJ that the record shows that R126 died within hours after the orders were given and that in fact the doctor's orders were being carried out. Fairfax App. Br. at 6.

The testimony relied on by Fairfax to show that the orders were being carried out was found by the ALJ to be vague, replete with generalities, and not credible in light of the complete failure of Fairfax to produce the results of the tests and x-ray the physician ordered, or a record entry showing the dispensing of the antibiotic he ordered. We agree and see no reason to disturb that credibility finding here. Moreover, as the ALJ recognized, the deficiency was not only in failing to carry out the orders, but in failing to chart what was done, "inasmuch as responsible and meaningful follow-up treatment would have been at peril, absent such vital information." ALJ Decision at 11; see Tr. at 157.

Fairfax's citations to R126's medical record to show that he was in extremely poor condition, died shortly after the orders were given, and was in a "do not resuscitate" status are also unavailing, even if true. Fairfax provided nothing to indicate that any of these factors affected the duty of care that Fairfax owed to R126, nor that anything that the ALJ found was expected of Fairfax under the circumstances was inconsistent with the plan of care for this resident. Thus, we agree with the ALJ that it is irrelevant that R126 would have expired in spite of treatment.

c. Substantial evidence in the record supports the ALJ's findings about R127, R83, and R68.

The ALJ found that Fairfax "failed to adhere to the guidelines it had adopted in March 1997 for ventilator dependent residents in respiratory distress by not monitoring or providing proper follow-up assessments to" R127, R83, and R68. ALJ Decision at 11-18.

Fairfax cited the record to show that R127 was also extremely ill and that the family's instructions were to provide only "comfort care." Fairfax App. Br. at 7-8. According to Fairfax, it was cited for deficiencies "where treatment and care were given with good results, but where documentation regarding subsequent monitoring was allegedly deficient according to Fairfax's new guidelines." *Id.* at 8. Similarly, with respect to R83, Fairfax asserted that "it is undisputed that Fairfax successfully treated this resident, but Fairfax was cited because it should have charted more frequently." *Id.* at 9.

As noted above, however, failure to document monitoring is a failure to meet the standard of care embodied in Fairfax's protocol and can have negative outcomes for the resident. The mere fact that the residents did not have negative outcomes in these particular instances is irrelevant. The records related to R127, R83, and R68 support the ALJ's conclusion that HCFA was not clearly erroneous in determining that the immediate jeopardy caused by Fairfax's failures had not been abated. The evidence shows (and indeed Fairfax does not dispute) that Fairfax was not consistently following its new protocol (based on the standard of care) for ventilator dependent residents suffering from respiratory distress.

Moreover, while emphasizing that only comfort care was to be provided for R127, Fairfax pointed to no evidence that comfort care would not include providing the care described in the protocol. The protocol on its face applies to any respiratory distress and indicates that one of the purposes of monitoring is to determine whether the resident is comfortable. P. Ex. 10.

d. Substantial evidence in the record supports the ALJ's findings about R6 and R11.

The ALJ found that Fairfax failed to ensure that R6 and R11 received proper tracheostomy care. ALJ Decision at 19-20. Fairfax made the point with respect to these residents that there is no evidence that they were ventilator dependent. This fact is relevant in determining whether the new protocol for ventilator dependent residents in respiratory distress applied to these residents. It does not, however, undercut the finding that, by failing to follow its own protocols (based on the standard of care) for residents needing special services, Fairfax was deficient in meeting the requirement at 42 C.F.R. 488.425(k). The particular special services at issue for these residents were tracheostomy care and tracheal suctioning. Part of one of Fairfax's protocols for such care may have been more important for ventilator dependent residents, specifically, oxygenating a patient before removing and cleaning a trach tube. However, the deficiencies found in Fairfax's care to these residents also related to other parts of its protocols, such as the need to use sterile technique.

Fairfax disputed the surveyor's testimony that its policy required use of hydrogen peroxide, rather than distilled water, as part of the sterile technique required. Fairfax App. Br. at 10, citing Tr. at 295. In support, Fairfax cited to HCFA Exhibit 21, which refers to sterile water, not hydrogen peroxide. The surveyor's finding, however, was based on a different Fairfax protocol, identified in the survey findings as "Procedure for Trach Care with Inner Cannula" and described as instructing the staff person to "clean outside of trach tube and surrounding skin area with hydrogen peroxide and normal saline using cotton tipped applicators." HCFA Ex. 1, at 27; see also Ex. 1 to HCFA App. Br. HCFA Exhibit 21 is titled "Sterile Suctioning of a Tracheostomy Tube." Fairfax did not dispute that it also had the policy on tracheostomy care described in the survey findings. Nor did Fairfax present any evidence to contradict the surveyor's testimony that the standard of care for cleaning the tracheostomy site is to use hydrogen peroxide. Tr. at 292-302. Also, contrary to what Fairfax implied, it is irrelevant that the surveyor admitted that she never determined whether R6 and R11 contracted any disease or infection as a result of the care given. As the definition of "immediate jeopardy" indicates, a showing of actual harm is not required.

We also note that the findings regarding these residents, while supportive, are not needed in order to uphold the conclusion in the ALJ Decision that Fairfax did not take adequate steps to abate the immediate jeopardy until April 3. As late as April 3, 1997, Fairfax was failing to meet the standard of care for monitoring R68, a ventilator dependent resident, after an episode of respiratory distress. See ALJ Decision at 17-18, and evidence discussed therein.

Conclusion

For the reasons explained above, we uphold the ALJ Decision. We affirm and adopt the ALJ's FFCLs.

Donald F. Garrett
Marc R. Hillson
Judith A. Ballard
Presiding Board Member

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION

No. C-97-406

FAIRFAX NURSING HOME, PETITIONER
v.
HEALTH CARE FINANCING ADMINISTRATION

Decision No. CR753
HHSDAB LEXIS 42

March 22, 2001

PANEL: Jose A. Anglada, Administrative Law Judge

OPINION:

DECISION

Fairfax Nursing Home (Petitioner) requested a hearing in this case on May 8, 1997, pursuant to section 1128A(c)(2) of the Social Security Act (Act) and 42 C.F.R. §§ 488.408(g), 498.3(b)(12),(13).[10] Petitioner is a skilled

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[1] **This matter was originally assigned to Administrative Law Judge Stephen H. Ahlgren. At the parties' request, the case was stayed for an indefinite period so that they could pursue settlement negotiations. On August 11, 1999, after months of inactivity, Judge Ahlgren ordered Petitioner to show cause why this case should not be dismissed for abandonment. In its response, Petitioner stated that it had not abandoned its request for hearing and that it had made several attempts to arrange settlement negotiations. On September 8, 1999, the case was reassigned to me. In the absence of objection, I allowed the case to go forward to hearing.**

nursing facility participating in Medicare and Medicaid. On April 8, 1997, the Illinois Department of Public Health (IDPH) completed standard, extended, and Life Safety Code surveys at Petitioner to determine if it was in compliance with the federal requirements for nursing homes participating in Medicare and Medicaid. That visit resulted in a finding that Petitioner was not in substantial compliance with participation requirements, and that the conditions in Petitioner's facility constituted immediate jeopardy to resident health and safety. As a result, IDPH notified Petitioner that it would recommend to the Health Care Financing Administration (HCFA) that it impose specific remedies. HCFA concurred with the recommendation and, on May 7, 1997, it imposed the following remedies:

> A civil money penalty (CMP) of $3,050 per day for each day of immediate jeopardy, effective December 20, 1996 and continuing through April 3, 1997; and a CMP of $50 per day, effective April 4, 1997 and continuing until attainment of substantial compliance or termination of the provider agreement.
>
> Directed Inservice Training, effective May 22, 1997 for all licensed nursing and certified respiratory therapy staff caring for the ventilator and tracheostomy residents.
>
> Denial of Payment for New Admissions, effective May 22, 1997.

HCFA subsequently determined that Petitioner was back in substantial compliance on May 15, 1997. HCFA imposed a CMP totaling $322,300, calculated as follows: a daily fine of $3,050 from December 20, 1996 through April 3, 1997 (a total of $320,250); and a daily fine of $50 from April 4, 1997 through May 14, 1997 (a total of $2,050).

Petitioner does not contest any of the deficiencies which were the basis of the $2,050 CMP from April 4, 1997 through May 14, 1997. Petitioner's Readiness Report at 1. At issue is HCFA's finding of immediate jeopardy, which is the basis of the CMP imposed from December 20, 1996 through April 3, 1997.

A hearing was held before me in Chicago, Illinois, from May 31 through June 2, 2000. At the hearing HCFA offered 21 exhibits identified as HCFA Ex. 1-21. Petitioner did not object to HCFA Ex. 1-20, and I admitted them into evidence. Petitioner objected to HCFA Ex. 21. I overruled Petitioner's objection, and admitted HCFA Ex. 21 into evidence. Petitioner offered 20 exhibits identified as P. Ex. 1-20. HCFA did not object to P. Ex. 1-20, and I admitted them into evidence. HCFA subsequently submitted a post-hearing brief (HCFA Brief). Petitioner submitted a response brief (P. Response). Attached to Petitioner's response brief is a May 26, 1998 final order and decision issued by IDPH. I identify this document as P. Attachment 1. Petitioner argues that the IDPH decision is instructive because it shows that the facts of this case "did not rise to the state equivalent of an immediate jeopardy." P. Response at 20. HCFA submitted a reply brief (HCFA Reply). Attached to HCFA's reply brief is a November 7, 2000 ruling issued by an Administrative Law Judge of this office. I identify this document as HCFA Attachment 1.

HCFA argues that reliance on the IDPH decision would be misplaced, and it cites the attached ruling as support for the proposition that I should refuse to defer to State administrative findings made in State proceedings where HCFA was not a party. The IDPH decision is not binding on me, and I accord it little weight. As HCFA points out, HCFA was never a party to the State proceedings and the State decision is the product of a different evidentiary record as well as different legal standards.

Based on the testimony offered at the hearing, the documentary evidence, the arguments of the parties, and the applicable law and regulations, I find that from December 20, 1996 through April 3, 1997, Petitioner was not in substantial compliance at the immediate jeopardy level. Thereafter, and continuing through May 14, 1997, Petitioner admits that it was not in substantial compliance at less than the immediate jeopardy level of severity. I find further that HCFA is authorized to impose CMPs against Petitioner at the rate of $3,050 per day from December 20, 1996 through April 3, 1997, and at $50 per day from April 4, 1997 through May 14, 1997.

Applicable Law and Regulations

Petitioner is considered to be a long-term care facility under the Act and regulations promulgated by the Secretary of the United States Department of Health and Human Services (Secretary). The statutory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act. The regulatory requirements are found at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act invest the Secretary with the authority to impose CMPs against a long-term care facility for failure by the facility to comply substantially with participation requirements. Pursuant to the Act, the Secretary has delegated to HCFA and the States the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. 42 C.F.R. Part 488 provides that facilities which participate in Medicare may be surveyed on behalf of HCFA by State survey agencies in order to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10 - 488.28. The regulations contain special survey provisions for long-term care facilities. 42 C.F.R. §§ 488.300 - 488.325. Under Part 488, a State or HCFA may impose a CMP against a long-term care facility where a State survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, 488.430. The penalty may start accruing as early as the date that the facility was first out of compliance and continue until the date substantial compliance is achieved or the provider agreement is terminated.

The regulations specify that a CMP that is imposed against a facility will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMPs, of from $3,050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1), (d)(2). The lower range of CMPs, of from $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. 488.438(a)(2). The terms "substantial compliance" and "immediate jeopardy" are defined terms in the regulations which govern participation of long-term care facilities in Medicare. "Substantial compliance" is defined to mean: "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. 488.301. "Immediate jeopardy" is defined to mean: "a situation in which the provider's non-compliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.*

There are additional factors which the State and HCFA consider in determining where within a range of penalties, once the range is established, the amount of a CMP should be. These include the facility's: 1. history of noncompliance, including repeated deficiencies; 2. financial condition; and 3. culpability for the deficiencies. 42 C.F.R. 488.438(f). Additionally, the State and HCFA may consider factors specified in 42 C.F.R. 488.404. These include the relationship that a deficiency may have to other deficiencies and a facility's prior history of deficiencies. The applicable burden of proof in a CMP case requires HCFA to prove a prima facie case that the facility has failed to comply substantially with one or more participation requirements. To prevail, a facility must overcome HCFA's showing by a preponderance of the evidence. *Hillman Rehabilitation Center*, DAB No. 1611 (1997); aff'd *Hillman Rehabilitation Center v. United States*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). HCFA's determination that a deficiency constituted immediate jeopardy must be upheld unless the facility proves that the determination was clearly erroneous. 42 C.F.R. 498.60(c)(2); *Woodstock Care Center*, DAB No. 1726, at 9 (2000).

The Act and regulations make a hearing before an Administrative Law Judge available to a long-term care facility against whom HCFA has determined to impose a CMP. Act, section 1128A(c); 42 C.F.R. §§ 488.408(g), 498.3(b)(12), (13). The hearing before an Administrative Law Judge is a de novo proceeding. *Anesthesiologists Affiliated, et al.*, 941 F.2d 678 (8th Cir. 1991).

Issues

1. Whether Petitioner was complying substantially with federal participation requirements on the dates HCFA determined to impose a CMP.

2. If it is established that Petitioner was not complying substantially with federal participation requirements, what was the level of non-compliance.
3. If non-compliance is established, whether the amount of the penalty imposed by HCFA is reasonable.

Findings and Discussion

Findings of fact and conclusions of law are stated below in italics. They are followed by a discussion of each finding.

1. *Petitioner was not in substantial compliance with federal participation requirements from December 20, 1996 through April 3, 1997.*

The applicable regulation at 42 C.F.R. 483.25, entitled "Quality of care," provides: "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan or care." As a corollary to this overarching requirement, 42 C.F.R. 483.25(k) provides that the facility "must ensure" that residents receive proper treatment and care for "special services," including: (1) tracheostomy care; (2) tracheal suctioning; and (3) respiratory care. Below, I will discuss examples of failures by Petitioner to comply with the pertinent regulatory requirements mentioned above.

Resident number 10 (R10)

a. Petitioner failed to implement a policy concerning ventilator dependent residents, and, through its carelessness, brought about the premature demise of R10.

This constitutes immediate jeopardy.

State surveyor findings

The findings of the State surveyors are set forth in a HCFA Form 2567. HCFA Ex. 1. In essence, the State surveyors found that the staff caring for R10 "did not follow guidelines/procedures/protocols in the provision of respiratory care, and that lack of adherence directly caused the death of R10." HCFA Ex. 1 at 21.

Discussion

The record shows that on December 20, 1996, R10 experienced an episode of respiratory distress and required care. Transcript (Tr.) at 135. She was completely dependent on a ventilator for breathing, as she could not do so on her own. Tr. at 138. Respiratory therapists administered oxygen to the resident using a device known as an ambu-bag. This device allows an operator to manually force air into the lungs in order to promptly raise the oxygen saturation level of a resident to normal. During the process of "ambu-bagging," a respiratory technician disconnected the resident from the ventilator, and turned the machine off.[11] After manually elevating the resident's oxygen saturation level, the therapist reconnected R10 to the ventilator, but did not turn the machine back on. This left the resident without any oxygen supply. She died as a direct result. Tr. at 135 - 138; HCFA Ex. 12.

Ms. Patricia Benda, the Director of Nursing (DON), was notified at home that R10 had died under questionable circumstances. Tr. at 479 - 480. She went to the facility

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[2] Disconnecting the resident from the ventilator is necessary for the manual administration of oxygen, but as will be discussed later, it is not necessary or desirable to turn the ventilator off.

and inquired as to the facts surrounding the death of R10, and learned that the ventilator had been turned off when R10 was being administered respiratory therapy. Ms. Benda was unable to obtain information as to who turned the ventilator off from the two attending respiratory therapists, Brenda Harris and Michael Anderson. The latter, who was the last person in the room with the resident, initially denied turning off the ventilator. Tr. at 480 - 482. The police were alerted and they came and took Mr. Anderson into custody. Under police interrogation, he stated that he "unconsciously" turned the ventilator off to silence its alarm while Ms. Harris was in the process of giving the resident manual respiratory therapy with an ambu-bag. The resident was returned to stable condition and everyone left the room. He was the last one out, and forgot to turn the ventilator back on. HCFA Ex. 12 at 7.[12]

Ms. Benda testified that Petitioner had a policy to the effect that the ventilator was never to be turned off unless the resident had been pronounced dead by a physician, or two registered nurses, or transferred to a hospital. Tr. at 484. If such a policy did exist, it appears to be an unwritten policy because no document containing that policy was produced at the hearing. It was not until February 1997 that Petitioner developed a written policy for the care and treatment of ventilator dependent residents in respiratory distress; and it was not until the beginning of March 1997 that, after much deliberation, the policy was implemented. That policy, entitled "Nursing Guidelines for

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[3] Mr. Anderson submitted his resignation shortly after this unfortunate incident, and before Petitioner took any action against him. Ms. Harris was terminated when it was discovered, several weeks later, that she had falsified her respiratory therapist certificate and credentials. Tr. at 607, 302 - 304.

Ventilator Dependent Residents in Respiratory Distress," was developed in the aftermath of the tragic events of December 20, 1996, involving R10. P. Ex. 10; Tr. at 491 - 492. The main purpose of those new guidelines was not only to ensure proper care and treatment for ventilator dependent residents who experienced respiratory distress, but also to provide monitoring for those whose respiratory distress symptoms had been relieved. Tr. at 510; P. Ex. 10.

Stabilized ventilator dependent residents were to be observed by a nurse and charted every fifteen minutes for up to an hour. The documentation would include vital signs, respiratory status, oxygen saturation levels, lung sounds, ventilator settings, level of consciousness, odor, color, and consistency of secretions, and comfort level of the resident. Any further respiratory distress noted during the monitoring period would warrant an immediate call to the attending physician, and continued observation and documentation throughout the shift, or until the resident stabilized or was transferred to a hospital. P. Ex. 10. Ms. Benda, the DON, agreed that the policy adopted by the facility after the incident of December 20, 1996 embodied good nursing practices, and that R10 should have been monitored after apparently having been stabilized. Tr. at 502.

It is unequivocal, from the facts of this case, that Petitioner's carelessness was the direct cause of R10's death. Tr. at 489. The lack of due care is first evident from the act of turning the resident's ventilator off, and then from not monitoring the resident after she apparently had been stabilized. As stated by Ms. Benda in her testimony, such monitoring is good nursing practice. She testified that it "should be done on every resident that goes into any type of distress." Tr. at 502. Furthermore, Petitioner did not have a written policy for the protection of ventilator dependent residents in respiratory distress. It is evident that whatever non-written guidelines existed were either improperly communicated to the attending staff or were not diligently applied.

Resident number 126 (R126)

b. Petitioner failed to carry out the treating physician's orders and failed to properly document R126's medical charts. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy.

State surveyor findings

On March 2, 1997, R126 was noted with an oxygen saturation level (SAO2)[13] of 80%, a temperature of 100.9, a pulse of 100, and respirations of 40. The treating physician was called, and treatment was prescribed for immediate administration. HCFA Ex. 1 at 22. The doctor ordered a chest x-ray,[14] start IV and antibiotics, instill blue dye into the tube feeding,[15] and elevate the head of the bed 45 degrees. There is no indication in the medical chart that these orders were carried out, nor is there a complete assessment of R126 as per facility guidelines. HCFA Ex. 1 at 22 - 23.

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[4] According to the treating physician, an SAO2 ranging from 92% - 100% is considered normal, and an SAO2 of 80% is dangerously low. Tr. at 40.

[5] The x-ray was aimed at determining if there were findings consistent with pneumonia, congestive heart failure, pneumothorax, or other abnormal lung conditions. Tr. at 32 - 33.

[6] A dye called methylene blue is placed into tube feedings to determine whether food is entering the lungs. Tr. at 35.

Discussion

Petitioner argues that R126 was admitted to the facility in a vegetative state, and that it is reasonable to conclude that his death was attributable to his very precarious condition. Tr. at 760. Specifically, it asserts that when the charge nurse noticed changes in the resident's condition she proceeded to take proper action. She began to monitor the resident and called the treating physician, who prescribed a course of treatment over the phone. Petitioner alleges that all of the doctor's orders were complied with, even though they were not charted. Finally, Petitioner contends that the issue of whether the antibiotic, Timentin,[16] was administered is specious, inasmuch as Dr. John Hardek, the treating physician, testified that it takes 24 hours for that medication to take effect. Tr. at 761 - 762.

Contrary to Petitioner's assertions, Dr. Hardek testified that in his opinion the resident died of pneumonia (Tr. at 47) and that, with treatment, the resident may have recovered from the pulmonary condition. Tr. at 35. It is Dr. Hardek's testimony that it would take time for the antibiotic to start working. Tr. at 47. However, this fact, rather than justifying a failure to administer it, serves to underscore the need for its prompt administration so that its therapeutic effects could be felt as soon as possible.

For the reasons set forth below, I find that Petitioner was woefully inadequate in the treatment and care of R126, in violation of 42 C.F.R. 483.25(k). Such conduct caused or was likely to cause serious injury, harm, impairment or death to the resident.

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[7] Timentin is a broad spectrum antibiotic. Tr. at 33.

The treatment and care charts for R126 do not reflect that any of Dr. Hardek's orders, telephonically relayed on March 2, 1997, were carried out. P. Ex. 9. It is unknown how much time transpired from when Dr. Hardek gave his instructions over the phone to when the resident passed away. From the totality of the record, it is reasonable to conclude that several hours passed. There is an indication in the record that the treating physician gave his orders during the morning portion of the nurse's 7:00 a.m. to 3:00 p.m. shift. Tr. at 335, 337. The progress notes have a "12 noon" insertion as to when the resident was found dead, but that entry is unreliable. P. Ex. 9 at 5. That insertion appears to have been made after the fact at some unknown date and time by the charge nurse, Ms. Tamilyn Lawrence, whose testimony, as will be seen below, was vague and replete with generalities.

As charge nurse, it was Ms. Lawrence's duty to follow through with Dr. Hardek's orders. She testified that she carried these out in the following way: "I believe we would have gotten the Timentin started. Otherwise, I would have called the doctor." Tr. at 342. She allegedly asked her Assistant Director of Nursing (ADON) to help her with the IV antibiotic, because: "I was busy doing other things. I had asked my ADON to at least -- to help me, and I guess we had discussed what would be better. She went to the emergency kit or she went to get the Timentin, and I was trying possibly to do other things, either go and call for the chest x-ray, and I think I sent an aide down to the kitchen to get blue dye for the tube feeding." Tr. at 342 - 343. Additionally, she "probably" asked the respiratory therapist to take samples for a sputum culture. Tr. at 364.[17]

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[8] While the HCFA Form 2567 does not specifically mention the sputum culture, the medical chart shows that Dr. Hardek ordered a sputum culture and stain. P. Ex. 9 at 7. The stain allows for immediate

Of all the orders given by Dr. Hardek, the only one Ms. Lawrence claimed that she did herself was the insertion of the blue dye in the feeding tube. Surprisingly, she could not say what the results were, nor did she make a record of it. Tr. at 343 - 344. She claimed that she was too busy to be able to provide for the needs of R126, but she made no specific mention of any particular task that took precedence over the care and treatment he required at that critical moment. Although Ms. Lawrence allegedly asked others for help, she could not say for certain whether the sputum samples were taken or whether the antibiotic was given.

If Ms. Lawrence had carried out all of the treating physician's orders herself, and had stayed by the resident's bedside monitoring him throughout his crisis, I might be more persuaded that there was an excuse for not documenting the medical charts. However, the only entry required of her was that of the administration of the blue dye test. The ADON, who allegedly administered the antibiotic, also failed to make an entry to that effect. Likewise, the respiratory therapist, who supposedly took the sputum sample, also failed to record the event. It would have been very easy for Petitioner to produce the results of the sputum tests and x-rays, the findings of the blue dye test, or an entry showing the dispensing of the antibiotic. Because it did not do any of these things, too many factors converge to detract from Petitioner's credibility regarding compliance with Dr. Hardek's orders.

Petitioner's argument that, even if it had fully complied with the treating physician's orders immediately the resident would still have died, is unavailing. A finding

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detection of bacteria, and the culture is grown in a microbiology laboratory. Tr. at 33.

of immediate jeopardy does not hinge on a showing of a direct causal relationship between the facility's failure to carry out the treating physician's orders and the death of the resident. Petitioner cannot argue that it did not immediately carry out the treatment and care prescribed for R126 because it knew that he would soon die. It is true that Petitioner was aware that R126 was extremely fragile and vulnerable, but that knowledge should have served as a catalyst for prompt and urgent action. The record presents a picture of a lackadaisical staff, rather than a staff aggressively treating a pneumonia that was further aggravating the resident's already compromised health. Even if the physician's orders had been carried out and not charted, that alone would have placed the resident at great risk, inasmuch as responsible and meaningful follow-up treatment would have been at peril, absent such vital information.

Matters are much worse here, however, in that there is not a shred of credible evidence that R126 was administered the treatment prescribed by his physician. That treatment was intended to treat a pneumonia, and as stated earlier, his treating physician identified that condition as the cause of death. It is irrelevant, as Petitioner argues, that R126 would have expired in spite of treatment. Petitioner had a duty with respect to R126 to administer the necessary care and treatment that would further R126's well being. Far from satisfying this requirement, Petitioner's actions, or lack thereof, had the potential to cause serious injury, harm, impairment, or death to the resident.

I also note that although R126 had a dangerously low SAO2 level at 80%, there is no documentation that he was suctioned or received respiratory therapy to increase his oxygen level. Ms. Lawrence testified that she recalled that R126 was suctioned, but had no recollection that ambu-bagging occurred or whether the oxygen levels on the ventilator were increased. Treatment or monitoring would be reflected in the progress notes or respiratory flow sheets, she said. Yet, she admits that the records fail to show that efforts were directed at increasing R126's SAO2 level. Tr. at 382 - 386.

Resident number 127 (R127)

c. Petitioner failed to adhere to the guidelines it had developed in February 1997, and implemented at the beginning of March 1997 for ventilator dependent residents in respiratory distress by not monitoring or providing proper follow-up assessments to R127. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy.

State surveyor findings

The State surveyors determined that on March 5, 1997, at 10:00 p.m., R127 was found pale, with mottled extremities, and an SAO2 of only 75%. There was no complete assessment of the resident, no vital signs were taken, no follow-up assessments every 15 minutes were done, and no physician was notified. HCFA Ex. 1 at 23.

On March 7, 1997, at an unknown time during the 7:00 a.m. to 3:00 p.m. shift, R127 was found cyanotic, requiring emergency ambu-bagging for five minutes. Nursing charted four follow-up notes, but only assessed R127's color and SAO2 levels. No vital signs or complete assessment were noted in the resident's record, as required by the guidelines. HCFA Ex. 1 at 23.

Respiratory Care made a note on March 7, 1997, during the 7:00 a.m. to 3:00 p.m. shift, that R127 had a total of three episodes in which the resident required emergency bagging for 10-15 minutes and experienced twitching and turning of her head back and forth. Her

SAO2 dropped to 82%. There is no indication that the treating physician was notified of the multiple episodes of respiratory distress. HCFA Ex. 1 at 23 - 24.

Again on March 10, 1997, there is a note by Respiratory Care, during the 7:00 a.m. to 3:00 p.m. shift, that R127 had another episode of turning blue, yet there is no nursing entry addressing respiratory distress and no vital signs or assessments were charted. HCFA Ex. 1 at 24.

On March 21, 1997, at an unknown time during the 7:00 a.m. - 3:00 p.m. shift, R127 was found with mottled legs, shaking, and SAO2 of 74%. The physician was there and she was ambu-bagged and given Valium. No complete assessments were done and follow-up [*25] was not carried out as per the guidelines. HCFA Ex. 1 at 24.

On March 25, 1997, R127 was found to have MRSA (methicillin-resistant staph aureus) in the sputum. R127 was found dead at approximately 7:45 p.m. on March 27, 1997. HCFA Ex. 1 at 24.

Discussion

Dr. Alberto Saltiel, R127's treating physician and Petitioner's medical director at the relevant time (Tr. at 62, 79), diagnosed R127 with pneumonia, and noted that she had been experiencing episodes of respiratory distress and convulsions. During the period preceding her death, he gave orders aimed at making the resident comfortable. This, he said, entailed raising the oxygen saturation level and stopping the seizures. Specifically, Dr. Saltiel stated that he directed that she be given respiratory therapy, Valium, and Dilantin. Nothing was prescribed for her pneumonia in view of her do not resuscitate (DNR) status.[18]

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[9] **Dr. Saltiel lay great emphasis on R127's DNR status. I would hope that such status is not at the root of the improper care and treatment given to this resident.**

Tr. at 65 - 73.

Doctor Saltiel testified that R127 was admitted to Petitioner after surgical removal of an esophageal diverticulum. Allegedly, she was also suffering from chronic obstructive pulmonary disease (COPD) which, in the treating physician's opinion, was terminal.[19] Doctor Saltiel further stated that the resident's family placed her in the nursing home for the purpose of receiving comfort care, and that nothing was to be done to prolong her life. In spite of that, it was Doctor Saltiel's opinion that R127 had lived beyond expectation.[20] Tr. at 64, 66.

Petitioner has presented no evidence to rebut HCFA's assertions that it failed to follow its own policy regarding the care and treatment of ventilator dependent residents in respiratory distress. In this respect, Dr. Saltiel's testimony not only confirmed the wisdom of the policy,[21] but also highlighted its ineffectual application. For example, on March 5, 1997, R127 was noted to have a pale color, mottled extremities, and an SAO2 of 75%.[22] The

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[10] I note, however, that COPD is not an admitting diagnosis for R127. P. Ex. 11 at 1.

[11] Regarding R127's clinical picture, I rely mostly on Dr. Saltiel's testimony inasmuch as the medical charts contain minimal charting by Dr. Saltiel. P. Ex. 11 at 9; Tr. at 63.

[12] Dr. Saltiel perceived that the policy for handling respiratory distress residents was good. To a certain extent, however, he deferred to the expertise of Dr. Sabbagh, whose knowledge as a specialist in pulmonary diseases he respected. Dr. Sabbagh was Petitioner's pulmonary specialist and he was instrumental in developing the policy for the care and treatment of respiratory distress residents. Tr. at 121, 491.

[13] It should be remembered that Dr. Hardek testified that an SAO2 of 80% was dangerously low. Tr. at 40.

progress notes show that she was ambu-bagged for five minutes and her SAO2 increased to 97%. The attending nurse noted that monitoring would continue. The record does not indicate how the monitoring would be done, nor is there documentation evidencing that monitoring was performed. P. Ex. 11 at 2.

Dr. Saltiel conceded that a resident who has experienced respiratory distress should be stabilized and monitored to ensure that return to normal functioning has in fact occurred. He also agreed that the guidelines for care and treatment of respiratory distress residents adopted by Petitioner called for monitoring every 15 minutes for a total of one hour. Tr. at 114-115. Such monitoring, as per the policy, encompasses vital signs, respiratory status, oxygen saturation level, lung sounds, ventilator settings, level of consciousness, odor, color, and consistency of secretions, and comfort level of the resident. P. Ex. 10. Such charting is absent from the progress notes of R127 during the various respiratory distress events mentioned by the surveyors in the findings noted above.

Although Dr. Saltiel appeared to recognize the virtues of the respiratory distress guidelines, he seemed confused regarding its application. Pertinent to this is his distorted understanding of the requirement to monitor a resident at 15-minute intervals for up to an hour after a respiratory distress event. When asked by counsel for HCFA whether or not the facility should have monitored R127 every 15 minutes on March 5, 1997, Dr. Saltiel responded that the resident was monitored more often than every 15 minutes. He added that just because the guidelines say that monitoring should be done every 15 minutes, it does not mean that it can't be done more often. In support of this statement, he referred to the entry at page 2 of P. Ex. 11, where it says that the resident was ambu-bagged for five minutes when she was found with an SAO2 of 75%.

Tr. at 115-116. Clearly, the intent of the guidelines is that, after being properly stabilized, a resident should then be monitored every 15 minutes for up to an hour. The number of minutes during which the resident is initially oxygenated bears no connection to the 15-minute interval monitoring after stabilization. The logic behind the conclusion that ambu-bagging for five minutes constitutes monitoring at less than the 15 minute interval called for in the policy escapes me.

Elsewhere, Dr. Saltiel testified that multiple crises of respiratory distress do not warrant notification of the treating physician as per the guidelines. On a personal level, he thought it would be a matter that he would like to be informed about. Tr. at 119. In saying this, he overlooked the language of the Nursing Guidelines for Ventilator Dependent Residents in Respiratory Distress. The last paragraph of page 1 of that document states as follows: "Any further respiratory distress will warrant an immediate call to the attending physician and continued observation and documentation throughout the shift, or until the resident stabilizes or is transferred to a hospital." P. Ex. 10 at 1.

Dr. Saltiel, as well as Ms. Carolyn Nealy, the respiratory therapist, acknowledged that R127 experienced multiple episodes of respiratory distress on March 7, 1997. Tr. at 117, 455-456. Notwithstanding the unequivocal requirement of the guidelines, Dr. Saltiel seemed unfazed by the fact that R127, his patient, had experienced a series of respiratory distress events on March 7, 1997, and he was not notified. P. Ex. 11 at 3. It is not clear whether R127 experienced respiratory distress on March 10, but she did have such an event on March 21, 1997. P. Ex. 11 at 3-4. As with respect to the earlier dates of March 5 and 7, no proper charting or monitoring, as required by the guidelines for respiratory distress residents, was performed. It is noteworthy that the progress notes show that on March 21, when R127 went into respiratory distress with an SAO2 of 74%, she was ambu-bagged by the therapist. P. Ex. 11 at 4. However, the therapist, Ms. Carolyn Nealy, testified that when she began to ambu-bag R127, Dr. Saltiel ordered her to stop because the resident was twitching and Dr. Saltiel said that the ambu-bagging would not relieve the twitching. Tr. at 462. That reasoning leaves me aghast since the therapist was not providing relief for the twitching, but for the respiratory distress. The incident is particularly disturbing in light of Dr. Saltiel's testimony that the respiratory distress caused oxygen decrease in the brain, and that, in turn, produced the convulsive reaction. Tr. at 68. It would appear logical, then, that the convulsions or twitching could be relieved by restoring oxygen to the brain through ambu-bagging.

At one point in his testimony, Dr. Saltiel stated that on March 21, 1997, R127 was treated according to the guidelines by improving her oxygen level. That, he said, would provide comfort for the resident. Tr. at 73. Ms. Nealy's testimony, which I believe to be true, establishes that what Dr. Saltiel did was make R127 suffer from lack of oxygen. I find Dr. Saltiel's testimony at pages 68 and 69 of the transcript, to the effect that his orders were directed at stopping the seizures with Valium and Dilantin, consistent with Ms. Nealy's testimony that the physician did not allow her to provide emergency oxygen to the resident. If the medical director had a flawed understanding of the application of the guidelines for handling respiratory distress residents, I am not surprised that the nurses and respiratory therapists displayed the kind of ignorance as to those same matters that permeate the record of this case.

I find the testimony of Ms. Joella Daniel, a surveyor, persuasive that Petitioner failed to monitor R127 during and after episodes of respiratory distress. This is particularly true on March 5, 7, and 21, 1997. From Ms. Daniels' testimony, I conclude that monitoring after ambu-bagging at successive intervals is crucial because an elevated SAO2 level immediately after oxygenation does not tell the true story of oxygen levels in the blood. The pulse, respiration, blood pressure, and temperature readings are some of the indicators of true stabilization. A resident's elevated SAO2 level immediately after ambu-bagging could be misleading. Thus, there is a need to continue close observation and scrutiny at successive intervals. Accurate recording in the progress notes of indicators such as those mentioned above will provide medical personnel vital information for the proper care and treatment of a respiratory distressed resident. On the other hand, the absence of such monitoring and charting of critical data regarding a respiratory distressed resident places that individual at risk for serious harm or death. Tr. at 171 - 175.

Also damaging to a resident could be the failure to notify the treating physician of such abnormalities as repeated episodes of respiratory distress. That is precisely what occurred on March 7, 1997. Petitioner's own policy states that more than one episode of respiratory distress warrants an "immediate call" to the treating physician. P. Ex. 10. In view of this, I do not give credence to Dr. Saltiel's testimony that repeated episodes of respiratory distress are not unusual, and therefore, impliedly of no serious concern. Tr. at 118-119. Ms. Daniels, on the contrary, considered that three episodes in one shift was significant and should have triggered notification of the treating physician. Tr. at 182-183. Likewise, Ms. Tamilyn Lawrence, one of Petitioner's nurses who had worked at Petitioner's facility since 1989, was of the opinion that three episodes in one shift requiring emergency respiratory care is not a common occurrence. She went on to agree that such a serious situation mandated adherence to the facility's respiratory distress protocol. Tr. at 392.

On cross-examination of Ms. Daniels, counsel for Petitioner tried to highlight that the record reflected that on those occasions in March 1997 when R127 went into respiratory distress, the treatment given brought about improvement in her condition. Tr. at 244-247. However, those references in the record indicating a positive response to treatment are not evidence that Petitioner carried out the assessments and monitoring at 15-minute intervals required by the guidelines. By failing to address the issue squarely, and pointing to irrelevant matters, Petitioner implicitly concedes that it ignored the application of its own policy. As stated earlier, its witnesses extolled the virtues of the policy, but few, if any, would live by it. Lip service falls far too short of the requirements. I find that Petitioner's failure to properly assess and monitor R127 during and after episodes of respiratory distress, as well as the failure to notify the treating physician regarding repeated episodes of respiratory distress, exposed the resident to risk of serious injury, harm, impairment, or death.

Residents 83 and 68 (R83 & R68)

d. Petitioner failed to adhere to the guidelines it had adopted in March 1997 for ventilator dependent residents in respiratory distress by not monitoring or providing proper follow-up assessments to R83 & R68. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy.

State surveyor findings (R83)

On March 23, 1997, at 8:30 a.m., R83 was found non-responsive. SAO2 was only 75% and vital signs were as follows: blood pressure 60/- (systolic only shown); pulse

100; respirations 12; and temperature 98.6. R83 was ambubagged and suctioned, with a large amount of thick, green-yellow sputum received, and the treating physician was called. The next entry was at 9:30 a.m., an hour later, noting that R83 was responding. This entry noted blood pressure, pulse, SAO2 level, and that an IV was started. The next and final follow-up entry was not made until 12:00 p.m., and it only noted blood pressure, pulse, and SAO2 level. HCFA Ex. 1 at 25-26.

Discussion

Ms. Daniels testified that on March 23, 1997, at 8:30 a.m., R83 was non-responsive to any verbal stimuli. The blood pressure reading only registered a systolic of 60, and the diastolic was so low that it was unobtainable. That would be indicative, she said, of a semi-shock state, where oxygen may not profuse throughout the body. She added that the pulse rate was 100 and the respirations were 12. The increased heart rate was the body's response to the lack of oxygen. She explained that, by pumping harder and faster, the heart tries to bring oxygen to the tissues. Tr. at 193 - 196.

The progress notes show that R83 had an SAO2 of 75%. From earlier references, it is known that this level of oxygen placed the resident at great risk. He was ambubagged and suctioned. The suctioning was productive of a large amount of green-yellow sputum. HCFA Ex. 16 at 2. The treating physician was called and orders were received. However, the charge nurse failed to specify what those orders were. The clinical picture presented by R83 is obviously that of a resident in respiratory distress. The situation should have triggered the application of the guidelines for respiratory distressed residents. Those guidelines had been adopted in early March 1997, and it is evident that, on March 23, the charge nurse continued to ignore its application. After R83 was ambu-bagged and suctioned at 8:30 a.m., no further clinical observations were recorded until 9:30 a.m. There was no monitoring at 15-minute intervals, as required by the guidelines for ventilator dependent residents in respiratory distress.

Again, Petitioner does not address its failure to apply the guidelines for ventilator dependent residents in respiratory distress. Those guidelines were intended to secure the best possible treatment for residents such as R83. Although his condition was extremely critical, and every minute counted, he remained unattended for an hour. It was not until 9:30 a.m. that he was treated with an IV. At that time his SAO2 had increased to normal or near normal range, and his blood pressure increased to 110/60. HCFA Ex. 16 at 2. The fact that he showed improvement does not excuse Petitioner's failure to follow the guidelines. That R83 survived Petitioner's incompetent care and treatment does not excuse the fact that he was placed at risk of serious injury, harm, impairment, or death.

State surveyor findings (R68)

On April 3, 1997 at 8:15 p.m., R68 became cyanotic with an SAO2 of 75%, requiring emergency ambu-bagging and increasing the FIO2 (fraction of inspired oxygen) on the ventilator to 40%. Nursing failed to make complete assessments and vital signs as indicated in the new guidelines. On April 4, 1997, Respiratory Care made a note that R68 was too unstable to perform routine tracheostomy change. HCFA Ex. 1 at 25.

Discussion

Petitioner's ventilator flow sheet for R68 reflects that on April 3, 1997, at 7:15 p.m., the resident was cyanotic and had an SAO2 of 71%. P. Ex. 12 at 8. The therapist ambu-bagged R68 with oxygen, but there is no indication that R68 was monitored thereafter in accordance with Petitioner's respiratory guidelines. Tr. at 229. Petitioner's records do not indicate whether R68's SAO2 level returned to normal after ambu-bagging or whether R68 was stabilized. The next record reference to R68 was not made until 8:15 p.m., an hour later. At that time, a nurse noted that R68 was again cyanotic with an SAO2 of 75%. Ambu-bagging was again performed. P. Ex. 12 at 3. While R68 was monitored at 15-minute intervals beginning at 8:15 p.m., the assessments omitted some vital sign information and other required evaluation data.

The record shows that, notwithstanding R68's extreme fragility, he did not have the benefit of care and treatment required for ventilator dependent residents in respiratory distress. Ms. Daniels testified that it was "pretty lucky" that nothing serious happened to R68, because, in a matter of minutes, brain damage could be sustained from lack of oxygen. Tr. at 230. Petitioner's duty to provide appropriate respiratory care to its ventilator dependent residents cannot be a matter of chance. It has to assure a resident the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and plan of care. 42 C.F.R. 483.25. I note, however, that the inability to perform routine tracheostomy care on R68 on April 4, 1997, is not indicative of a deficiency on the part of Petitioner.

Residents 6 and 11 (R6 & R11)

e. Petitioner failed to ensure that R6 and R11 received proper tracheostomy care. This had the potential for serious injury, harm, impairment, or death to the residents and constitutes immediate jeopardy.

State surveyor findings

On April 2, 1997, the surveyor observed an employee at Petitioner's facility perform tracheostomy care on R6 And R11 without using sterile procedures and without hyper-oxygenating[23] the residents prior to or after suctioning. HCFA Ex. 1 at 26 - 27.

Discussion

HCFA contends that the failure to apply sterile suctioning procedures runs counter to Petitioner's own policy. HCFA Ex. 21; Tr. at 734. Specifically, Ms. Benton-Babatunde, a surveyor, testified that the employee providing tracheostomy care to R6 and R11 used an improper solution to clean the trachea prior to initiating suctioning procedure. The employee used the same solution to clear the catheter after suctioning as well as during the process. By using the same solution to clear the suctioning tubing as well as to clean the area around the tracheostomy site, the affected resident is put at great risk of having bacteria introduced into the trachea and lungs. The result, stated Ms. Babatunde, could be pneumonia or sepsis, where the bacteria traveling through the circulatory system causes generalized body infection. Tr. at 297 - 298. Proper hygiene is especially critical in the case of nursing home residents, due to their high level of susceptibility to pneumonia and other infections. More significantly, they are more vulnerable to the more virulent types of pneumonia. Tr. at 55, 298.

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[14] Hyper-oxygenation is a procedure whereby the ventilator dependent resident is manually given added oxygen prior to and after suctioning. This makes up for the oxygen deprivation during the suctioning process. Tr. at 294 - 295.

The surveyor's findings also indicated that the employee providing tracheostomy care to R6 and R11 failed to hyper-oxygenate the residents prior to or after suctioning. Petitioner addressed this with the testimony of Ms. Joyce Casares, a nurse. She testified that hyper-oxygenation of the resident is not necessary because the facility has a "closed system" of respiratory therapy. With that system it is not required to remove the resident from the ventilator during suctioning. Tr. at 415-416. At a later point in her testimony, however, she conceded that during suctioning no air would be able to enter the lungs. In that case, even in the presence of a "closed system," the oxygen deprivation would appear to justify hyper-oxygenation. Tr. at 428-429. This testimony was contradicted by another of Petitioner's witnesses, Ms. Benda. Ms. Benda indicated that in a "closed system" the ventilator dependent resident is not deprived of oxygen at any time during suctioning. Tr. at 497 - 498.

In addition to the above, there is another inconsistency noted between the testimonies of Ms. Benda and Ms. Casares. Whereas Ms. Casares (who worked at Petitioner's facility for 27 years), stated that the so called "closed vent system" had been in place at the facility since "almost the very beginning" (Tr. at 415), Ms. Benda stated that at the time of the incidents leading up to this case, the "closed system" was fairly new to the field of respiratory therapy. Tr. at 496.

In rebuttal, HCFA recalled Ms. Benton-Babatunde to the stand. She stated that during the survey of the facility, Petitioner presented her with a policy titled "Sterile Suctioning of a Tracheostomy Tube." HCFA Ex. 21; Tr. at 734. That policy addressed the kind of suctioning procedure performed with the equipment observed by Ms. Benton-Babatunde on April 2, 1997. That policy did not refer at all to the "closed system" suctioning method mentioned by Ms. Casares and Ms. Benda. More importantly, the guidelines made available to the surveyor went to great lengths to explain the proper way to perform sterile suctioning and how to properly hyper-oxygenate a resident. If, as Ms. Benda testified, the closed system was new, it could not have been in place since "almost the very beginning," as alleged by Ms. Casares. On the other hand, if it was new, it was not yet in use at the time of the survey in question. At best, it could have been in the process of being phased in, but on the day of the survey, Ms. Benton-Babatunde did not see that "new" system. She only saw the method that requires hyper-oxygenation, and Petitioner gave her the policy that applied to that type of suctioning procedure. Moreover, Mr. Jesus Rodriguez, the director of respiratory care, testified that staff would hyper-oxygenate a resident if it were deemed to be needed. It was a clinical judgment, he said. Tr. at 556. He appeared to recognize the existence of a suctioning method that could call for hyper-oxygenation, even though his testimony was a departure from the suctioning protocol adopted by the facility that mandated hyper-oxygenation. This evinces Petitioner's poor dissemination of its policies to the staff. It is particularly disconcerting that those in supervisory positions were so ill-informed.

In view of the foregoing, I find Ms. Benda's and Ms. Casares' testimony regarding the suctioning method employed at Petitioner on April 2, 1997, not credible. Ms. Benton-Babatunde's testimony is more consistent with the evidence of record and deserving of probative value. In reaching this conclusion, I must also say that Petitioner presented no reliable evidence to discredit the surveyor's testimony that in the tracheostomy care of R6 and R11, it failed to apply proper sterile suctioning technique and it did not ventilate the residents with enriched oxygen, as required by its own policy guidelines. HCFA Ex. 21. The deficient tracheostomy care provided to R6 and R11 placed them at risk of serious injury, harm, impairment, or death.

Resident Number 130 (R130)

f. The conduct of Petitioner with respect to R130 does not constitute a deficiency.

State surveyor findings

On March 17, 1997, at 1:00 a.m., R130 complained of a swollen neck and difficulty breathing. The respiratory therapist attempted suctioning, but the results were unproductive. Respiratory treatment was then given, along with Ativan, as needed. No complete assessment was done, nor were vital signs taken. HCFA Ex. 1 at 25.

Discussion

I note from the record that R130 had an SAO2 of 96% at 1:00 a.m. on March 17, 1997, and was not in respiratory distress. P. Ex. 14 at 5; Tr. at 75, 412. Thus, no lack of compliance may be attributed to Petitioner regarding the treatment and care of a respiratory distressed resident arising from its handling of R130.

2. Beginning December 20, 1996 and continuing through April 3, 1997, Petitioner failed to comply with the requirements of 42 C.F.R. 483.25 at the immediate jeopardy level.

During the period beginning December 20, 1996 and ending April 3, 1997, Petitioner failed to comply with the regulatory requirements of 42 C.F.R. 483.25 by exposing its residents to risk of serious injury, harm, impairment, or death. This regulation provides that a long-term care facility must ensure that residents receive proper treatment and care for special services, including tracheostomy care, tracheal suctioning, and respiratory care. The evidence in this case establishes that Petitioner failed to provide its residents with the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being. HCFA proved that on December 20, 1996, Petitioner did not have a written policy to protect its ventilator dependent residents who went into respiratory distress. Moreover, notwithstanding the absence of written guidelines, Petitioner's supervisory staff expressed awareness of the proper procedures for tracheostomy and respiratory care, but did not communicate these to the nursing staff or to respiratory therapists. Tr. at 397, 484, 522, 523, 556-558.

Petitioner claims that the incident that resulted in the death of R10 was an isolated accident. Tr. at 324. That, Petitioner reasons, diminishes its level of culpability. I disagree. As stated earlier, the respiratory therapist attending to R10 did not accidentally turn off her breathing machine. He deliberately turned it off so as not to be inconvenienced by the sound of the machine's alarm while another therapist was in the process of manually elevating the resident's SAO2 level. True, he may have accidentally left the machine turned off, but such oversight is not to be taken lightly or ignored. It resulted in the death of a human being. That is not to say that Mr. Anderson's conduct was criminal in nature, as Petitioner also claims. P. Response at 17. There is no evidence in the record that he was held criminally liable for the death of R10. He was, however, clearly negligent in turning the respirator off so as not to be bothered by the alarm. By turning it off, he placed himself at risk of forgetting to turn it back on after manually elevating the resident's oxygen level. Mr. Anderson's action is more connected with Petitioner's failure to have clear and written guidelines that were effectively communicated to its employees than with criminal intent.

Petitioner argues also that I should give weight to a visit made by IDPH surveyor Margaret White shortly after

R10's death. Petitioner argues that Ms. White's failure to find an immediate jeopardy at that time creates an inference that no immediate jeopardy existed. The record shows that Ms. White visited Petitioner on January 2, 1997. She was at Petitioner for about two hours and looked only into the facts concerning R10. Tr. at 621 - 622. Ms. White left that day without issuing a written statement of deficiencies. Instead, she indicated that she was still gathering facts. She stated that she had to wait for the police report and she needed to consult with more people. Tr. at 622-623, 679. Moreover, at the time of Ms. White's visit, a more thorough annual survey was expected to be conducted. Tr. at 521. That survey was completed on April 8, 1997. By that time, all of the evidence concerning R10 was available. In view of the foregoing, I do not accept Petitioner's claim that Ms. White's failure to make findings in January 1997 invalidates the later finding of immediate jeopardy based on the more complete information gathered by April 8, 1997.

Furthermore, the evidence establishes that Petitioner failed to protect other residents from similar acts until April 4, 1997. It was not until April 4, 1997, that Petitioner had taken adequate steps to train its staff regarding the treatment and care of ventilator dependent residents. The record shows that by April 4, 1997, Petitioner had taken the following the actions:

1) A new protocol was initiated for assessment, care, and follow-up of ventilator dependent residents in respiratory distress.

2) Immediate one-to-one training regarding the newly developed guidelines for all respiratory care and nursing staff.

3) 24-hour management supervision of staff was initiated.

4) A new policy was initiated concerning the hiring of respiratory therapists, and their qualifications and training.

5) A new skills/procedural checklist for ventilator dependent residents was developed to assess each licensed and respiratory care staff member. Checklist assessment was initiated on April 4, 1997, for all working personnel, to be completed each shift. The assessment would continue until all staff was assessed.

See HCFA Ex. 1 at 31.

From December 20, 1996, until the above abatement actions were initiated, Petitioner took minor steps to comply with its duty to care for and protect ventilator dependent residents, but fell short to the point of continuing to place them at risk of serious injury, harm, impairment, or death. For example, I note that on December 23, 1996, three days after the incident involving R10, Petitioner conducted a 20 minute in-service concerning matters of notification of death in such cases. On January 8, 1997, Petitioner conducted another in-service regarding the operation of the respiratory ventilator. P. Ex. 8. These training sessions fell far too short of satisfying what was required to abate the immediate jeopardy.

Petitioner's additional claim that it took immediate corrective action on December 20, 1996, by hiring Mr. Jesus Rodriguez, a certified respiratory therapist, to consult with Petitioner about the care provided to ventilator dependent residents, is without merit. Basically, all that action accomplished was to replace the lost services of the former director of the respiratory care unit, who had left due to medical problems. Tr. at 676. Besides, Mr. Rodriguez's testimony accentuates the facility's failure to properly communicate its policies to the staff. As I stated earlier, the testimony of Mr. Rodriguez regarding sterile suctioning of a tracheostomy tube highlighted his ignorance in this important area of resident care. I specifically stated how disturbing it was that those in supervisory positions were so ill-informed. Thus, no corrective measures were, in reality, advanced by bringing in a new respiratory care director or consultant who carried on the facility's history of ignorance concerning respiratory care.

This ignorance is further evidenced by Petitioner's argument at page 19 of its brief. Its fragmented view of the requirements for proper care and treatment of residents in respiratory distress leads to the following faulty reasoning: Although R10 was being given care by staff, she was found unresponsive within 15 minutes of the last time she was with staff. HCFA's claim that monitoring R10 every 15 minutes would have resulted in her still being alive does not stand up to the facts in this case. Despite being given care by a respiratory therapist as late as 1:00 a.m., R10 was unresponsive by 1:15 a.m. P. Brief at 19. This logic overlooks factors such as mentioned by Ms. Daniels, one of the surveyors, in her testimony. She stated that once you raise a resident's oxygen level, you cannot rest assured that stability has been achieved. It is essential to note indicators required by Petitioner's written policy, such as vital signs and lung sounds. Tr. at 171-175. If the staff had taken R10's respirations, pulse reading, blood pressure, lung sounds, and other required indicators, they would have surely noted she was not breathing. This reasoning also ignores the testimony of Ms. Benda, Petitioner's DON. She agreed that the policy adopted by Petitioner in early March 1997 for the care and treatment of ventilator dependent residents in respiratory distress, embodied good nursing practices, and that R10 should have been monitored after having been apparently stabilized. Tr. at 502.

Those guidelines were developed to ensure that a ventilator dependent resident who experienced any form of respiratory distress would be "observed" by the nursing staff and respiratory therapy department and properly treated and "relieved of her/his respiratory distress and documented on." P. Ex. 10 at 1. The documentation includes indicators such as blood pressure, pulse, respiration, temperature, lung sounds, and breath sounds. These indicators would serve as verification that a resident in respiratory distress, whose oxygen level has been increased, has achieved true relief. Once that is accomplished, follow-up assessment and documentation is mandated every 15 minutes. P. Ex. 10. If this procedure had been followed with respect to R10, the tragedy that unfolded would have been prevented.

In Petitioner's attempts to immediately address the circumstances that gave rise to the tragedy of December 20, 1996, involving R10, other weighty factors, including the adoption of written guidelines for the treatment and care of ventilator dependent residents in respiratory distress, were not considered. In this regard, Ms. Daniels testified that, after R10's demise, the lack of the facility's immediacy in initiating a protocol to prevent any further problems placed other residents who had episodes of respiratory distress at severe risk for harm, if not death. This, in her estimation, constituted immediate jeopardy. Tr. at 232.

Petitioner began to take more serious steps to address its duty to properly treat and care for ventilator dependent residents in respiratory distress in early March 1997, when it adopted guidelines for treatment of such residents. Unfortunately, however, no training was conducted in earnest, and residents continued to be placed at risk of serious injury, harm, impairment, or death, even after those guidelines were adopted. This is evident from the previous discussion regarding the improper treatment and care given to R126, R127, R83 and R68. The treatment and care given to these residents was contrary to the policy adopted by Petitioner in early March 1997, for the treatment and care of ventilator dependent residents in respiratory distress. Thus, they continued to be placed at risk throughout the month of March and through April 3, 1997. As already stated, it was not until April 4, 1997, that Petitioner initiated a comprehensive plan to address and abate the immediate jeopardy.

In view of the foregoing, I conclude that there is a basis to impose a CMP against Petitioner in the immediate jeopardy range for the period which begins on December 20, 1996, and which runs through April 3, 1997. HCFA satisfied all of the prerequisites for imposing such a penalty. First, HCFA established a prima facie case, which Petitioner did not rebut, that as of December 20, 1996, Petitioner was not complying substantially with the participation requirement at 42 C.F.R. 483.25. Indeed, there is not only a prima facie case of noncompliance here, but the preponderance of the evidence is that Petitioner was not complying substantially with this requirement. Second, Petitioner failed to show that HCFA's determination that Petitioner's noncompliance with this requirement was at the immediate jeopardy level was clearly erroneous. In fact, the preponderance of the evidence establishes that Petitioner's deficiency was at the immediate jeopardy level. Third, Petitioner did not prove by the preponderance of the evidence that it had eliminated the immediate jeopardy to its residents on any date prior to April 4, 1997.

3. The amount of the penalty imposed by HCFA is reasonable. HCFA imposed a $3,050 per day CMP for the period beginning December 20, 1996 and ending April 3, 1997. There is no issue as to the reasonableness of the

daily amount of the penalty inasmuch as $3,050 is the minimum that may be imposed by HCFA where it is established that the participating facility has incurred a deficiency that reaches the level of immediate jeopardy. 42 C.F.R. 488.438(a)(i). HCFA also imposed a $50 per day CMP for the period beginning April 4, 1997 and ending May 14, 1997. There is no issue in this case as to whether a CMP of $50 per day for the period from April 4, 1997 through May 14, 1997 is reasonable. Petitioner has not contested the presence at its facility of deficiencies at less than the immediate jeopardy level during that period. A CMP of $50 per day for deficiencies that posed a potential for more than minimal harm to residents, but not at the immediate jeopardy level, is the minimum for such deficiencies. 42 C.F.R. 488.438(a)(ii).

Conclusion

I conclude that HCFA correctly determined that beginning December 20, 1996 through April 3, 1997, Petitioner was not complying with federal participation requirements in the Medicare program at the immediate jeopardy level, and the imposition of a CMP of $3,050 per day is reasonable. I also conclude that from April 4, 1997 through May 14, 1997, HCFA properly assessed a $50 per day CMP for deficiencies that posed a potential for more than minimal harm, but not at the immediate jeopardy level.

Jose A. Anglada
Administrative Law Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
APPELLATE DIVISION

Nos. A-96-157, C-95-159

HILLMAN REHABILITATION CENTER, PETITIONER,
v.
HEALTH CARE FINANCING ADMINISTRATION, RESPONDENT.

DAB No. 1611
1997 HHSDAB LEXIS 547

February 28, 1997

CORE TERMS: provider, clinical, patient, signature, surveyor, regulation, billing, certification, burden of proof, termination, burden of persuasion, therapist, opt, accessible, prima facie case, monthly, involvement, noncompliance, preponderance, beneficiary, coming, patient record, substantial compliance, physical therapy, central office, incomplete, faxed, contemporaneous, progress, rehabilitation

PANEL: Cecilia Sparks Ford, M. Terry Johnson, Judith A. Ballard, Presiding Board Member

OPINION:

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

The Health Care Financing Administration (HCFA) appealed a May 22, 1996 decision by Administrative Law

Judge (ALJ) Steven T. Kessel. *Hillman Rehabilitation Center*, DAB CR419 (1996) (ALJ Decision). Hillman Rehabilitation Center (Hillman) had sought a hearing before the ALJ challenging HCFA's termination of Hillman's participation in the Medicare program for substantial noncompliance with federal requirements for outpatient physical therapy and rehabilitation agencies. The ALJ concluded that HCFA had failed to establish a basis for terminating Hillman's participation.

As discussed below, we conclude that the ALJ erred in determining that HCFA had the ultimate burden of persuasion. While we reject some of HCFA's arguments, we conclude that HCFA established a prima facie case that Hillman was not complying substantially with the two conditions of participation at issue. We further conclude that, on the record before us, Hillman did not meet its burden of proving by a preponderance of the evidence that it was in substantial compliance with the conditions. We have determined, however, that Hillman may have been prejudiced by ALJ errors in assigning the burden of proof, in analyzing the evidence, and in ruling on evidentiary issues, and that Hillman should have an opportunity to proffer additional evidence to meet its burden. Therefore, we remand the case for further proceedings consistent with this decision and our instructions below.

I. BACKGROUND

A. Factual summary

Hillman Rehabilitation Center has provided outpatient physical therapy (OPT) in New Jersey with Medicare certification since about 1985.[24] Its business

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[1] **Here we provide a brief statement of the facts which are not contested, except as indicated. Matters which were the subject of factual dispute are discussed where relevant in the analysis sections.**

office is in Lakewood but the vast majority of treatments to patients are provided by therapists working for Hillman who operate out of rented offices in eight long-term care facilities (LTCs) around the state. The original treatment records for these patients are maintained in the LTCs.

HCFA contracts with the New Jersey Department of Health to perform periodic compliance surveys of participating providers. On January 13, 1995, a State surveyor visited Hillman's central office to perform a periodic survey of Hillman's compliance with Medicare conditions of participation (COPs). This and the subsequent surveys were conducted only at the central office in Lakewood, and did not include visits to any of the LTCs. Hillman's administrator was not present during the January 1995 survey, but the surveyor met with the office manager. Hillman was found out of compliance with a number of conditions of participation at that survey, including the COP for maintaining clinical records. HCFA Exs. 3, 4, 5. Hillman submitted a plan of correction. Uncontradicted testimony indicated that a revised plan of correction was ultimately accepted (although the accepted plan was not submitted for the record).

On February 22, 1995, the surveyor returned for a follow-up survey. After that survey, the State survey agency prepared a report showing that the violations had been corrected. HCFA Exs. 8, 9. The parties disputed whether the certification of Hillman after the February revisit constituted an indication that Hillman's record-keeping system was then acceptable or reflected reliance on Hillman's written promise in correspondence after the revisit that it would update its central office records monthly in the future. See HCFA Ex. 10.

On April 5, 1995, the surveyor returned to Hillman's office in Lakewood, along with a representative of the Medicare fiscal intermediary, Aetna. At that visit, some records were reviewed and photocopied. As a result of this visit, Hillman was found deficient and given until May 5, 1995 to submit an acceptable plan of correction.[25] Since no acceptable plan was received as of that date, Hillman was terminated effective July 5, 1995. HCFA Ex. 15. HCFA terminated Hillman because it determined, based on the State survey results, that Hillman could not be certified due to substantial noncompliance with two COPs for rehabilitation agencies.[26] The two relevant COPs relate

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[2] Hillman did not dispute that it had not provided a plan of correction as of the required date, but argued that it had requested an extension (evidenced by a letter dated May 5, 1995, the same day the correction plan was due). P. Ex. 5. Hillman received no reply to this request and submitted a proposed plan dated May 19, 1995, two weeks late. P. Ex. 6. The State surveyor's supervisor testified that the extension was not given because such requests are not traditionally granted and because Hillman's track record did not justify it. Hearing Tr. 172; see also Hearing Tr. 75. Both the surveyor and his supervisor testified that the plan as submitted was unacceptable, as well as untimely. Hearing Tr. 75-76, 173; HCFA Ex. 12 (Hillman's proposed plan with annotations by the supervisor dated May 23, showing unacceptable points).

[3] The regulations provide that state surveyors are "professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance." 42 C.F.R. 488.26(b)(3). A state survey agency is required to certify that a provider is not in compliance with the COPs "where the deficiencies are of such character as to substantially limit the provider's . . . capacity to render adequate care or which adversely affect the health and safety of patients." 42 C.F.R. 488.24(a). In determining compliance, the state agency is to consider "the manner and degree" to which a provider satisfies each standard in a COP and to document "the nature and extent of deficiencies, if any." C.F.R. 488.26(a). A provider found deficient in one or more standards under the COPs may participate in Medicare only if it "has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time" and if its deficiencies do not "jeopardize" patient health and safety or "seriously limit" its capacity to render adequate care. 42 C.F.R. 488.28(a). [***Lengthy material in footnote omitted. For complete text, see 1997 HHSDAB LEXIS 547 (1997).]

to (1) physician involvement in planning and delivering care [42 C.F.R. 405.1717] and (2) maintenance of complete and accurate clinical records [42 C.F.R. 405.1722]. P. Ex. 7 (HCFA Termination Letter, June 13, 1995).

Hillman sought review of HCFA's determination to terminate its participation as provided by 42 C.F.R. 488.24(a) and received a hearing before an ALJ as provided by 42 C.F.R. 498.40 et seq. The hearing regulations require the provider to specify in its hearing request "the specific issues, and the findings of fact and conclusions of law" with which it disagrees and the "basis for contending" that they are wrong. 42 C.F.R. 498.40(b). A party dissatisfied with an ALJ's decision after the hearing may seek review before the Departmental Appeals Board (DAB), as HCFA has done in this case. 42 C.F.R. 498.80 et seq.

B. The ALJ Decision

The ALJ Decision contained six numbered findings of fact and conclusions of law (FFCLs) as follows:

1. HCFA has the burden of proving that Petitioner failed to comply with a condition of participation in Medicare.
2. The Act and regulations require Petitioner to maintain clinical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.
3. Petitioner is not obligated to maintain at its Lakewood, New Jersey, business office complete and contemporaneous copies of records of treatments that it provides at eight long-term care centers.

4. The account by the New Jersey State Agency surveyor of his April 5, 1995 visit to Petitioner is not credible.
5. HCFA did not prove that Petitioner failed to comply with the condition of participation governing plans of care and physician involvement in the planning and delivery of care contained in 42 C.F.R. 405.1717.
6. HCFA did not prove that Petitioner failed to comply with the condition of participation governing clinical records contained in 42 C.F.R. 405.1722.

ALJ Decision at 3-4.

C. HCFA's Exceptions

HCFA appealed five of the six FFCLs in the ALJ Decision. HCFA Br. at 5-6. Since neither party excepted to FFCL 2, it is summarily affirmed. HCFA contended that the ultimate burden of proof remained on the provider to demonstrate by a preponderance of the evidence that it was in substantial compliance with federal requirements. HCFA argued that the ALJ erred in interpreting the clinical records requirements not to require copies of off-site records to be maintained at the central office, but further argued that this interpretation was irrelevant here, since the ALJ found that the provider was obligated to produce records at the central office when requested by a surveyor regardless of the location of the records (for example, by facsimile transmission). Hence, HCFA argued that Hillman should have been found out of compliance, without regard to where its records were filed, based on the survey finding that complete records were not available when requested. *Id.* at 6-7.

HCFA argued that the entire case "hinges" on the ALJ's erroneous conclusion that the State agency surveyor did not request patient clinical records during the April 5th survey, since the ALJ stated that Hillman's versions of the patient clinical records would otherwise be "self- serving exhibits" with "little or no probative value." *Id.* at 9. HCFA argued that the ALJ's conclusion about the survey events was founded on factual findings not supported by the record and disregarded other evidence tending to undercut the credibility of Hillman's version of events. *Id.* at 7-8. HCFA argued that the ALJ, having accepted Hillman's version of events at the April survey, then erred further by relying uncritically on Hillman's patient record exhibits rather than HCFA's exhibits to evaluate Hillman's compliance with the COPs as of the survey date. *Id.* at 9-10. HCFA also contended that the ALJ erred in accepting the existence of a distinction between the billing file' and the clinical file' drawn by Hillman's lone witness. *Id.* at 7.

Further, HCFA claimed that it was prejudiced by errors in the ALJ's rulings on certain evidence. Specifically, HCFA argued that the ALJ precluded evidence from HCFA relating to what the Aetna representative was seeking at the April 5th survey, while allowing Hillman to present evidence on that issue. *Id.* at 8.

D. Standard of review on appeal

Our standard for review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard for review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. We must thus uphold the ALJ's findings of fact "if a reasonable mind reviewing the evidence in the record as a whole could accept it as adequate to support his conclusion." *Consolidated Edison v. NLRB*, 305 U.S. 197, 229 (1938); *Richardson v. Perales*, 402 U.S. 389, 401 (1971). However, the substantiality of the evidence must be weighed in light of whatever in the record detracts from as well as whatever supports each finding. See *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951); see also *Walker v. Mathews*, 546 F.2d 814, 818 (9th Cir. 1976).

E. Guide to our decision

The analysis in our decision is divided into two major components. First, we discuss the correct allocation of the burden of proof. Second, we address the disputed issues on the merits of this case. The main sections of our discussion can be found on the following pages.

ANALYSIS OF THE BURDEN OF PROOF

A. Summary of major conclusions

B. The ALJ failed to clearly distinguish the burden of going forward and the ultimate burden of persuasion.

C. The structure and purpose of the Medicare program and the role of certification and of provider agreements support our analysis.

D. The ALJ's allocation of the burden of proof is inconsistent with relevant case precedent and relies on analogies to types of cases that are inapposite.

E. Hillman's due process attack is without merit.

F. The underlying concerns reflected in the ALJ analysis can be met without placing the ultimate burden of persuasion on HCFA.

ANALYSIS OF THE MERITS OF THE CASE

A. Summary of major conclusions

B. The ALJ's conclusion that Hillman's patient record exhibits were the best evidence of its compliance on April 5, 1995 is not supported by substantial evidence or reasonable inferences therefrom.

C. The factors cited by the ALJ in accepting Hillman's version of survey events are neither supported by substantial evidence nor based on reasonable inferences, and other relevant factors were disregarded without adequate explanation.

D. Noncompliance with the physician involvement condition of participation

E. Noncompliance with the clinical records condition of participation

Finally, we set out our conclusions and disposition of the exceptions to the FFCLs and our instructions to the ALJ on remand.

II. ANALYSIS OF THE BURDEN OF PROOF

A. Summary of major conclusions

HCFA took exception to FFCL 1, which stated: HCFA has the burden of proving that Petitioner failed to comply with a condition of participation in Medicare. We conclude that the ALJ erred in determining that HCFA had the burden of proof (in the sense of the ultimate burden of persuasion) in this proceeding. We reverse the ALJ's conclusion in FFCL 1 and substitute the following FFCLs:

> FFCL 1A. HCFA must set forth the basis for its determination terminating a provider with sufficient specificity for the provider to respond, including the

basis for any finding that a condition-level deficiency exists. The provider must then identify which of the findings material to the determination the provider disputes, and must also identify any additional facts the provider is asserting.

FFCL 1B. At the hearing, HCFA has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case that HCFA had a legally sufficient basis for termination.

FFCL 1C. At the hearing, the provider has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

FFCL 1D. The provider bears the ultimate burden of persuasion. To prevail, the provider must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with the relevant statutory and regulatory provisions.

The major reasons for our conclusions, explained below, are:

a) The rationale for the ALJ's conclusion regarding burden of proof failed to distinguish clearly the burden of going forward from the ultimate burden of persuasion, and misconstrued the effect of requiring HCFA to make a prima facie case.

b) Congress authorized payments to be made to rehabilitation agencies only if they qualified--not only by filing a provider agreement, but also by meeting applicable conditions of participation, as shown by an affirmative determination of compliance, generally made by HCFA on the basis of state survey agency findings. A mere determination on appeal that it is only "as likely" that the conditions were substantially met as that they were not met could result in payment contrary to statutory intent. The purpose of the conditions--to protect the health and safety of the patients who are the intended beneficiaries of the program--requires that an affirmative determination of substantial compliance be made.

c) Contrary to what the ALJ found, there is no distinction, relevant for who bears the burden of proof, between a provider first seeking to participate in the program and a provider whose agreement is terminated. The provider agreement is not a contract which should be presumed to continue in effect unless HCFA can prove at a hearing that its terms were violated. The provider's obligation to meet the conditions of participation in order to qualify for payment does not arise from the agreement, but from the statute. While HCFA must make a determination consistent with the statutory and regulatory requirements for termination of a provider agreement, that determination alone is a basis for termination, effective on the date set by HCFA in the notice of its determination. In any event, a provider agreement by itself is not sufficient to show that payment under the statute is authorized. Under the regulations, a finding of noncompliance supersedes any previous certification.

d) The ALJ's allocation of the burden of proof is inconsistent with the relevant case precedent and relies on analogies to types of cases that are inapposite.

e) Hillman's reliance on cases involving due process issues is misplaced. Nothing in the due process cases requires that HCFA bear the burden of persuasion here. Contrary to what Hillman implied, the courts have not found any provider expectation of continued participation that outweighs HCFA's interest in protecting the patients and program. At most, they have held that a provider has a right to reasonable notice and an opportunity for a hearing, which in most cases can be satisfied by a post- termination hearing or an informal pretermination hearing followed by a post-termination evidentiary hearing.

f) The underlying concerns reflected in the ALJ analysis can be met without placing the ultimate burden of persuasion on HCFA.

B. The ALJ failed to distinguish clearly the burden of coming forward and the ultimate burden of persuasion.

In discussing burden of proof, it is important to distinguish the "burden of coming forward with evidence" (also known as the "burden of production"), which may shift between the parties during the case depending on the order of proof and the particular issues in dispute, and the "ultimate burden of persuasion" which determines the outcome of a case when the evidence is in equipoise. 7/ See *Director, Office of Workers' Compensation Programs, Dept. of Labor v. Greenwich Collieries*, 512 U.S. 267 (1994). Effectively, the ALJ placed on HCFA both the burden of coming forward with evidence that would establish a prima facie case that the provider had failed to comply substantially with a COP and the ultimate burden of persuasion that such failure had occurred.

The prehearing order stated that HCFA would "have the burden of coming forward with evidence proving by a preponderance of the evidence that Petitioner failed to comply substantially" with the Medicare COPs, and also stated Petitioner would "have the burden of rebutting evidence offered by HCFA, to the extent that HCFA establishes a prima facie case," as well as the "burden of proving any affirmative arguments that it alleges." Order and Notice of Hearing at 2-3. The ALJ erred in assuming that the requirement that HCFA come forward with evidence establishing a prima facie case implies that HCFA bears the ultimate burden of proving substantial noncompliance by a preponderance of the evidence. This error was made even more explicit in the final ALJ Decision, where the ALJ stated that since "HCFA has obtained the evidence that it believes justifies" termination, HCFA should be put "to the test of proving that its determination is supported by a preponderance of the evidence." ALJ Decision at 4.

HCFA did not dispute that it has the burden of coming forward with evidence establishing a prima facie case that Hillman substantially failed to comply with program requirements. This is appropriate because HCFA's determination to terminate a provider agreement must be legally sufficient under the statute and regulations. We agree with the ALJ that HCFA must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

HCFA contended, however, that it was inconsistent with the statutory goal of protecting Hillman's patients--the intended beneficiaries of the program--to place the ultimate burden of persuasion on HCFA. Our analysis of the relevant statutory and regulatory provisions leads us to the same conclusion. As we explain below, the ALJ erred because he misconstrued the nature of the provider agreement and the effect of a prior certification. As we further explain, the ALJ's rationale for his conclusions regarding burden indicates that he also failed to consider other relevant factors and based his determination on concerns that, while valid, can be met without placing the ultimate burden of persuasion on HCFA.

C. The structure and purpose of the Medicare program and the role of certification and of provider agreements support our analysis.

The statute and regulations, read as a whole, compel the conclusion that the ultimate burden of persuasion must rest on the provider. We discuss here the nature and purpose of the program and relevant parts of the major provisions supporting our conclusions. Medicare is a benefits program, intended to provide health insurance for the aged and disabled. Since Medicare involves an exercise of Congress' spending authority, funds may be expended only for authorized payments. The statute authorizes payments for particular types of items or services (provided to eligible individuals). Restrictions on payment are contained in the service definitions, in definitions of terms incorporated in those definitions, and in other statutory provisions.

For example, section 1832(a)(2)(C) of the Act authorizes payments for certain "outpatient physical therapy services." The term "outpatient physical therapy services" is defined in section 1861(p) of the Act. This definition excludes services furnished by a "rehabilitation agency" like Hillman unless the rehabilitation agency meets certain conditions specified in the statute, as well as "other conditions relating to the health and safety of individuals . . . , as the Secretary may find necessary, ..." Section 1861(p)(4)(a). Section 1835(a) of the Act specifies that payment for outpatient physical therapy services may be made: 1) only if certain requirements are met (such as requirements for plans of care); and 2) "only to providers of services who are eligible therefor under section 1866(a) . . . ."

Section 1866(a) sets out requirements for provider agreements. Having a provider agreement is not enough to qualify for program participation, however. The lead-in language to section 1866(a)(1) states: "Any provider of services . . . shall be qualified to participate . . . and shall be eligible for payments . . . if it files with the Secretary an agreement . . . " (Emphasis added.) The term "provider of services" includes a rehabilitation agency only if such "agency meets the requirements of section 1861(p)(4)(A)"-- the conditions mentioned above-- and "only with respect to the furnishing of outpatient physical therapy services (as therein defined) . . . ." Section 1866(e) of the Act (emphasis added); see also section 1861(u) of the Act; 42 C.F.R. 405.1701.

In sum, a rehabilitation agency that is not a "provider of services" is not qualified to participate in Medicare (whether or not it has a provider agreement), nor would services provided by such an agency meet the statutory definitions of services for which Congress has authorized payment. Moreover, the Act and regulations set out a survey and certification process requiring an affirmative finding that a provider substantially meets the conditions of participation. The Secretary may use an appropriate state or local agency to determine whether providers meet relevant conditions of participation. Specifically, the Secretary may use such an agency "for the purpose of determining . . . whether a . . . rehabilitation agency . . . meets the requirements of subparagraph A . . . of section 1861(p)(4)." Section 1864 of the Act. An "agency that such a State or local agency certifies is a [particular type of provider] (as those terms are defined in section 1861) may be treated as such by the Secretary." *Id.* (emphasis added).

Under the implementing regulations, "certification" is a "recommendation made by the State survey agency on the compliance of providers . . . with the conditions of participation . . . ." 42 C.F.R. 488.1; see 42 C.F.R. 488.12. On the basis of a state survey agency's recommendations, HCFA will determine whether "a provider is eligible to participate in" Medicare. Thus, unless a provider has been certified as meeting the appropriate requirements, it is not qualified for purposes of Medicare participation and payment.

In the case of a provider which had previously been certified, the state agency will certify that the provider "is not or is no longer in compliance with the conditions for participation . . . where the deficiencies are of such character as to substantially limit the provider's . . . capacity to render adequate care or which adversely affect the health and safety of patients . . . ." 42 C.F.R. 488.24(a). Under the regulations, a "State survey agency certification to HCFA that a provider . . . is no longer in compliance with the conditions of participation . . . will supersede the State survey agency's previous certification." 42 C.F.R. 488.20(c). Additional statutory and regulatory provisions support a conclusion that: 1) prior certification should not be a basis for presuming the provider is qualified; 2) the health and safety of the program beneficiaries is paramount; and 3) the effective date of a termination is determined by HCFA and may be prior to an evidentiary hearing.

Under the Act, the Secretary-- may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary-- (A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this title and regulations thereunder, . . . , (B) has determined that the provider fails substantially to meet the applicable provisions of section 1861, or (C) has excluded the provider from participation in a program under this title pursuant to section 1128 or 1128A.

Section 1866(b)(2) of the Act (emphasis added). Section 1866(b)(3) provides that a termination of an agreement shall be effective on same date and in the same manner as an exclusion from participation under section 1128(c) of the Act (that is, "at such time and upon such reasonable notice . . . as may be specified in regulations . . . "). Implementing regulations provide that the effective date of a termination is the date specified in a termination notice issued by HCFA. 42 C.F.R 489.53. Generally, notice must be given at least 15 days prior to the effective date, with shorter notice in cases of immediate jeopardy to patient health or safety. Similarly, section 1866(c)(1) of the Act provides:

Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, such provider may not file another agreement under this title unless the Secretary finds that the reason for the termination or non-renewal has been removed and that there is reasonable assurance that it will not recur. An institution or agency dissatisfied with either a determination that it is not a provider of services or a determination to terminate its provider agreement "is entitled to a hearing thereon (after reasonable notice) to the same extent as is provided in section 205(b)" of the Act. Section 1866(h)(1) of the Act. HCFA regulations at 42 C.F.R. Part 498 establish the procedures for appeal of either type of determination, whether the institution or agency had previously been certified or not. Although these regulations do not specify who has the burden of proof (in either sense), these regulations treat HCFA's determination as an "initial determination" (rather than merely a proposal) that is binding unless reconsidered by HCFA or reversed or modified on appeal. 42 C.F.R. 498.20(b).

Considering the Act and regulations read as a whole, we conclude that a mere determination on appeal that it is only "as likely" that the conditions of participation were substantially met as that they were not met (as could be the effect of placing the ultimate burden on HCFA) could result in payment contrary to statutory intent. As HCFA argued, the purpose of the conditions is to protect the health and safety of the patients who are the intended beneficiaries of the program, and this interest outweighs any interest the provider might have in program participation. Congress provided that an affirmative determination certifying compliance must be made for a provider to qualify. Contrary to what the ALJ suggested, the posture of the provider seeking review of a HCFA determination that the provider no longer complies with the conditions of participation (i.e., where the provider was previously certified) is not distinguishable from the posture of a provider refused an initial certification, except that reasonable notice (as defined in HCFA regulations) must be given before the effective date of a termination of an agreement based on a previous certification. That certification, however, is automatically "superseded" by the state survey agency finding of noncompliance. Thus, this is not a situation where the hearing is to determine whether a previously granted certification should be revoked, nor is it equivalent to a license revocation.

The provider agreement is not a contract which should be presumed to continue in effect unless HCFA can prove at a hearing that its terms were violated. The provider's obligation to meet the conditions of participation in order to qualify for payment does not arise from the agreement, but from the statute. The primary function of the provider agreement is so that the otherwise qualified provider can provide certain necessary assurances about its participation in the program. Yet, a provider agreement by itself is not sufficient to show that payment under the statute is authorized. The burden remains on the provider to show that it continues to qualify under the Act and regulations.

Under the statute and regulations, it is Hillman which seeks through its request for review of HCFA's determination to change the status quo. While HCFA must make a determination consistent with the statutory and regulatory requirements for termination of a provider agreement, that determination is a basis for termination, effective on the date set by HCFA in the notice of its determination. Thus, Hillman was terminated as a provider prior to this appeal and seeks to overturn its termination and to be certified retroactively as in compliance. Like a prospective provider filing a provider agreement for the first time, Hillman here is the proponent of an order certifying it as qualified to participate in the program and to receive Medicare payment for services rendered, so it is fair to place the ultimate burden of persuasion on Hillman.

D. The ALJ's allocation of the burden of proof is inconsistent with relevant case precedent and relies on analogies to types of cases that are inapposite.

Contrary to what the ALJ Decision suggested, allocation of burden of proof is a matter of substantive law, not simply procedural flexibility. Greenwich Collieries, supra. Thus, the ALJ erred in relying on regulations granting the ALJ discretion to determine order of presentation to conclude that the ALJ had discretion regarding how the burden of proof should be allocated. 14/ In determining burden of proof, the ALJ must act within the legal framework and constraints discussed above. An allocation which would permit Medicare payments when it is no more likely than not that the provider complied with the applicable conditions of participation is simply not an appropriate allocation of the burden.

The Board has not previously addressed the burden of proof issue, contrary to what Hillman argued here. However, prior decisions by the Appeals Council of the Social Security Administration--which reviewed ALJ decisions in these cases prior to 1993--interpreted the statute and regulations as requiring allocation of the ultimate burden of persuasion to the provider. Jefferson Memorial Hospital Assn, Docket No. PS-109, at 17 (SSA Appeal Council 1983); see also Harry D. Lawson, D.P.M., Case No. 010-00-0002, at 2 (ALJ Prehearing report and order, April 5, 1983) (HCFA must establish a prima facie case; ultimate burden of proof remains with the provider who is "proponent" of a decision reversing HCFA's initial determination); Extenda Care Home Health Agency, Docket No. 000-51-7198 (ALJ Decision 1993) (HCFA must show prima facie case, provider has ultimate burden of proof in termination case). These decisions evidence a long- standing interpretation, which Congress has not acted to overturn.

The ALJ misconstrued the Appeals Council decisions. See *Arecibo Medical Hospice Care*, DAB CR363, at 12 (1995); see also *Hospicio en el Hogar de Lajas*, DAB CR366, at 8 (1995). Instead, the ALJ and Hillman relied on analogies to other types of cases. This reliance is misplaced, however. Those cases are inapposite, for the following reasons: Contrary to what the ALJ concluded, terminating Medicare provider participation is not equivalent to terminating disability benefits to someone previously found to have been eligible for such benefits. There are programmatic and other reasons for presuming that a disability continues (and the intended program beneficiaries should continue to receive payments) unless it is proven otherwise. Those reasons do not apply here.

Contrary to what Hillman argued, Medicare provider termination cases are not analogous to health care program exclusion and civil money penalty cases brought by the Inspector General in which the government bears the burden of proof. Hillman Br. at 15; see section 1128 of the Act. Different due process concerns are implicated in those cases, because they involve allegations of wrongdoing and may involve questions of intent. Moreover, the effect of an exclusion is like a debarment: it bars participation in multiple government programs for a period of time, irrespective of whether the excluded individual or entity is qualified and providing covered services. On the other hand, Medicare providers may be terminated for reasons that do not bear on the integrity or reputation of the provider, and thus do not impugn any protected liberty interests. Compare Gonzales v. Freeman, 334 F.2d 570 (D.C.Cir. 1964). A terminated provider may be reinstated in the program whenever it demonstrates that the reasons for termination no longer exist and provides adequate assurances that the deficiencies will not recur.

As HCFA argued, a more appropriate analogy would be cases involving termination of a Head Start grant. In those cases, this Board has held that the agency terminating a Head Start grantee must make a prima facie case that there exists sufficient evidence to satisfy the regulatory standards for termination but that the grantee has the ultimate burden of persuasion. See, e.g., Richmond Community Action Program, Inc., DAB No. 1571, at 6-7 (1996); see also Rural Day Care Ass'n of N.E. North Carolina v. ACF, DAB No. 1489, at 8 (1994), aff'd Civ.

No. 2:94-CV-40-BO (E.D.N.C., Dec. 19, 1995) (unpublished). Like those cases, the case here raises the issue whether conditions for receipt of federal funds have been met.

E. Hillman's due process attack is without merit.

Hillman argued that due process considerations here supported allocating the ultimate burden of proof to HCFA. Hillman argued that, as a provider rather than an applicant, it had a contractual relationship with HCFA, which constituted a property interest subject to constitutional due process protections. Hillman's due process arguments are misplaced. These arguments, like the ALJ Decision, rest on a contractual analysis which fails to recognize the role of the statute and regulations in determining Hillman's rights. Hillman has received due process in the form of an uncontested entitlement to a formal hearing before the ALJ. Hillman did not argue that it was entitled to a formal hearing prior to its termination, and such an argument would fly in the face of the express provisions of the Act, discussed above. Courts have held that a provider has no due process right to a pre-termination hearing, even where termination might effectively end the business: [T]he "death" of a corporation does not warrant the degree of protection required for a welfare recipient, or even a disability recipient. This is especially true since patients receiving Medicare or Medicaid benefits are the intended beneficiaries, and [the provider] is a mere incidental beneficiary. Furthermore, the government's interest in conserving scarce resources and protecting Medicare and Medicaid recipients is much stronger than the financial interest of a corporation.

Northwest Healthcare, L.P. v. Sullivan, 793 F. Supp. 724, 727-28 (E.D. Tex. 1992). All of the considerations supporting the denial of any hearing prior to termination also undergird the analysis here that would place the burden on a provider to show that it is more likely than not that it is in compliance with the conditions required for certification. The issue before us is whether under the statute and regulations the provider is due a process in which the government has the ultimate burden of proving noncompliance by a preponderance of the evidence. None of the cases cited by the ALJ or Hillman remotely suggests that a terminated provider's due process rights extend beyond receiving a full and fair hearing to include specifically how the burden of proof should be allocated in such a hearing.

Courts have rejected the notion that a Medicare provider has a property interest in an expectation of continued participation. In Cervoni v. Sec'y of Health, Education and Welfare, 581 F.2d 1010, 1010-14 (1st Cir. 1978), a physician challenged the determination that his clinical laboratory services would be compensated under Part B rather than Part A of Medicare, which he claimed would reduce his income, without due process. The Medicare classification scheme does not, the court found, affect "interests that properly may be classified as property." 581 F.2d at 1018. Further, the court held that "the real parties in interest are the beneficiaries" and that physicians "do not have a protectable property interest in their continuing eligibility to bill for reimbursement." *Id.* Prior receipt of payment did not imply a continuing promise or valid expectation of continued eligibility. 581 F.2d at 1018-19; cf. *Kelly Kare v. O'Rourke*, 930 F.2d 170 (2d Cir.), cert. denied 502 U.S. 907 (1991) (home health provider has no property interest in continuing qualified provider status under Medicaid).

We conclude that Hillman did not demonstrate any constitutionally-protected due process interest sufficient to justify altering the burden of proof in cases involving terminated providers from that applicable to providers denied initial certification. Absent certification based on substantial compliance with the conditions of participation, no category of provider is qualified to participate in Medicare.

F. The underlying concerns reflected in the ALJ analysis can be met without placing the ultimate burden of persuasion on HCFA.

The ALJ stated that, apart from due process concerns addressed above, assigning the burden of proof to HCFA would be "efficient." ALJ Decision at 4. The basis for this was that HCFA had possession of the evidence on which it was relying and that it would be unreasonable to require a provider "to prove a negative proposition--that it did not fail to comply with a condition of participation--in the absence of proof that it failed to comply with that condition of participation" or to respond to shifting arguments by HCFA. *Id.* The ALJ further stated: "If HCFA has a burden of coming forward with evidence, but no burden of persuasion, then HCFA has neither an obligation nor an incentive to make even a prima facie case to justify its determination . . . . Indeed, under HCFA's theory, Petitioner could offer evidence which might rebut completely whatever evidence HCFA opts to offer, but which would fail to overcome the presumption of validity which HCFA asserts attaches to its determination . . . ." ALJ Decision at 5.

It is traditional (and based on fundamental fairness), in deciding who has the burden of proof, to consider who has control of relevant information. The reasoning that the ultimate burden of persuasion should be on HCFA because it gathered the evidence of noncompliance does not apply here, however. Any evidence which HCFA has came from a survey of Hillman's own records and facilities, and

Hillman is the one in possession of the most complete evidence of the state of its compliance. While it was fair to require HCFA to come forward with the evidence of noncompliance which HCFA obtained from Hillman, it is unfair under the circumstances to place the ultimate burden of persuasion on HCFA.

Similarly, we find no basis for concluding that HCFA would somehow lack the incentive to make a prima facie case simply because HCFA does not have the ultimate burden of persuasion. If HCFA has the burden of coming forward with evidence sufficient to establish a prima facie case and does not do so, then HCFA would lose even if the provider presents no evidence. We understand the ALJ's concern about a HCFA position suggesting that all HCFA had to do was to present what its determination was, without providing the underlying basis for the factual findings. Often, survey findings are cursory and HCFA determination letters conclusory. Unless HCFA fully discloses and presents the basis for its findings of noncompliance, placing the ultimate burden of persuasion of showing substantial compliance on the provider would put the provider in the position of presenting all the evidence it has relevant to any COP at issue, even if HCFA's evidence would not ultimately be contradictory. This concern is fully met by placing the burden on HCFA of coming forward with evidence establishing a prima facie case.

The argument that the provider cannot be asked to prove a negative is largely a matter of semantics. The burden can be phrased positively: the provider must prove that it complied with any conditions which HCFA determined were not met or that any deficiencies do not justify termination. The concern that the provider would be forced to present a massive and unfocused case defending its status is best addressed by requiring HCFA to make the basis for its action specific enough for the provider to respond. The provider need not address every requirement for certification but only those requirements which HCFA determined the provider did not meet and, as to those, demonstrate by a preponderance of the evidence only that any basis for termination established in HCFA's prima facie case does not exist. We are not persuaded by Hillman's argument that HCFA has shifted its arguments and allegations in this case, illustrating why the burden should be on HCFA and how impossible it would be "to anticipate all those arguments to present a case at the outset." Oral Argument Tr. 18- 19. The rule we adopt here requires HCFA to make its case at the outset, addressing Hillman's major concern. Moreover, to the extent that HCFA made any new arguments, Hillman had ample opportunity to respond.

Finally, we note that the ALJ may meet some of the concerns for efficiency by other means, such as requiring HCFA to present all of its evidence initially, even with respect to facts asserted by a petitioner. There may also be such efficiency concerns in a situation where a petitioner does not deny that the deficiencies alleged, if found, would together justify termination, but offers proof that not all of those deficiencies existed and that any ones that did exist would not justify termination. The ALJ could reasonably, in such a situation, require HCFA to present any counter-evidence as part of its case- in-chief. We note, however, that evaluating whether deficiencies substantially limit a petitioner's ability to provide adequate care or adversely affect patient health and safety is not a purely evidentiary question. The relevant statutory and regulatory requirements reflect congressional and administrative determinations relevant in evaluating what is necessary to ensure adequate care and patient health and safety. If the petitioner does not prove that it was substantially complying with these requirements, this may be sufficient to establish that termination was justified.

III. ANALYSIS OF THE MERITS OF THE CASE

A. Summary of major conclusions

We find that the ALJ drew inferences in evaluating the significance of Hillman's patient record exhibits that are not supported by the record as a whole. Specifically, in considering whether Hillman's exhibits were the best evidence of the state of its compliance on the date of the April 5, 1995 survey, the ALJ accepted two explanations by Hillman of why more complete records were not produced on that date (if then extant); we find these explanations mutually inconsistent and not supported by substantial evidence in the record. Further, the ALJ ignored intrinsic evidence of unreliability of Hillman's exhibits for the purposes for which they were offered. In reaching his conclusions about Hillman's exhibits, the ALJ relied heavily on his determinations about the events of the April 5th survey. His assessment of the plausibility of the two accounts was not based on the demeanor of the witnesses, but rather on factual findings and inferences which were not supported by substantial evidence in the record, and ignored other relevant facts.

We conclude below that Hillman had the burden of proving as an affirmative argument that more complete records were readily available on April 5, 1995 which would have demonstrated substantial compliance with the COPs but were not produced because the surveyors' document request was too limited. Based on the present state of the record, we would find that there is not substantial evidence to support a conclusion that Hillman proved by a preponderance of the evidence that records more complete than those produced at the survey were readily accessible (either in distinct clinical files or in the

LTCs) on April 5, 1995--which would have demonstrated substantial compliance with the COPs. However, our review of the proceedings below indicates that it may not have been clear to the parties that Hillman bore both the burden of coming forward with evidence and the burden of persuasion on this issue. Therefore, we adopt an FFCL clarifying the burden of proof, and in our instructions below provide for an opportunity to Hillman to proffer additional evidence.

Absent other proof, the patient record exhibits which Hillman produced at the hearing are not reliable evidence of what clinical records were readily accessible on the survey date. However, this would not suffice to make Hillman's patient record exhibits irrelevant to assessing its compliance with the plan of care and physician involvement COP. Even if not readily accessible, Hillman's records could evidence the involvement of physicians, if they could be shown to be a reliable picture of the condition of records (in terms of physician signatures and completion). In addition, other evidence of physician oversight and timely completion of clinical records extrinsic to the records themselves could establish substantial compliance. It does not appear from the proceedings below that the parties clearly understood the relevance of such evidence beyond the question of which set of records should be considered by the ALJ. Therefore, in our instructions, we provide an opportunity for Hillman to proffer evidence to meet its burden of proof on this COP by either demonstrating that its patient record exhibits are reliable evidence of the condition of its clinical records on April 5, 1995 (even if not readily accessible) or producing other extrinsic evidence of compliance.

Turning to the specific COPs at issue, we find that, while HCFA's interpretation of the requirements for physician review of plans of care to require review at the outset of the plan of care is reasonable, it was not the only reasonable interpretation of the provision. Hillman's alternative interpretation that such review was required within 30 days of the beginning of treatment was not unreasonable, and HCFA did not give sufficient notice of its interpretation. The ALJ concluded that, even accepting HCFA's interpretation, Hillman was in compliance based on its own exhibits because he found that they all had plans of care signed by a physician and most also had written orders for OPT, either of which sufficed to show physician review. We conclude Hillman's compliance should be weighed against its interpretation of the requirements. However, we determine that Hillman's exhibits are not reliable and sufficient evidence of its compliance as of April 5, 1995. We determine that Hillman has the burden of showing that it was in compliance as of April 5, 1995. Hence, Hillman must either show that its exhibits reliably demonstrate compliance as of that date or it must otherwise demonstrate compliance as of that date by extrinsic evidence.

In regard to the clinical records COP, we determine that the ALJ's conclusion that contemporaneous filing of copies of clinical records in the central office is not required does not support a finding that Hillman was complying with the requirement to have readily accessible records. On the contrary, Hillman's production of incomplete records in response to surveyors' requests establishes a prima facie case that completed records were not readily accessible. We agree with HCFA and the ALJ that the regulations require prompt completion (meaning within 14 days of generation of the entry) of all clinical entries requiring a physician signature. The ALJ concluded that the regulations do not expressly require the physician to date entries except for progress reviews of plans of care. However, since we hold that Hillman has the ultimate burden of proof, we conclude that Hillman had to show prompt completion of the requisite entries in order to support a claim of compliance based on timely completion. Absent contemporaneous dating by physicians, the burden is on Hillman to demonstrate by other reliable and probative evidence that the records were in fact completed promptly. The ALJ found, and we agree, that Hillman's own exhibits evidence late, undated, and missing physician signatures. See ALJ Decision at 26-27. The ALJ found that HCFA had not sufficiently proven that the deficiencies rose to the level of noncompliance with a condition of participation because, relying on Hillman's exhibits as the more credible, he found no "pattern" or "wholesale failure" to obtain physician signatures. Again, this conclusion is premised on the erroneous assumption that HCFA had the ultimate burden to prove such a pattern or wholesale failure rather than that Hillman had the burden to show either that physicians did timely complete the records or that any failure to do so was not substantial enough to violate the condition.

B. The ALJ's conclusion that Hillman's patient record exhibits were the best evidence of its compliance on April 5, 1995 is not supported by substantial evidence or reasonable inferences therefrom.

A central dispute in this case is what inferences the record supports concerning the probative value, if any, of the treatment records proffered by Hillman. HCFA argued that Hillman's patient record exhibits were wholly irrelevant because they were not the records produced at the April survey and were therefore not the measure of Hillman's compliance at the time of the survey. 19/ Hillman argued that its compliance should be measured only on the basis of its exhibits, because the surveyor did not make a sufficiently clear request at the April survey for complete clinical records. The ALJ concluded that Hillman's exhibits were authentic and inferred that they must therefore be the best evidence of the state of Hillman's compliance. Consequently, the ALJ entirely disregarded (as mere excerpts) the patient records obtained at the survey and submitted by HCFA. We find neither of these extreme positions fully supported on the record as a whole.

Hillman's exhibits purport to be more complete clinical records for the same patients whose records (as obtained at the April survey) were offered by HCFA to show the inadequacy of Hillman's clinical records and the lack of [*47] required physician involvement. HCFA's exhibits consisted mostly of records for treatments in January and February 1995 (as well as some dating as far back as September 1994) which contained spaces for physician signatures and dates that were not completed. See, e.g., HCFA Ex. 17-35. Hillman's exhibits included additional records about the same patients' treatments during roughly the same periods, and, in many instances, contain records identical to ones in HCFA's exhibits but with initials or signatures added on the physician lines, most of them without accompanying dates.

The obvious question is why Hillman would produce on the date of the survey copies of incomplete patient records (for example, orders for treatment and plans of care lacking physician signatures), if in fact it had completed copies of these documents readily accessible as required. Hillman offered two somewhat inconsistent explanations for this: (1) that the completed records were available but were not in the Lakewood office and that the surveyors were told so and indicated that was acceptable, or (2) that the surveyors asked only for "billing" records and failed to request patients' clinical records which would have included the completed records. We discuss each theory in turn and then turn to a review of Hillman's patient record exhibits themselves to assess their intrinsic reliability.

1) Hillman repeatedly represented that its records were forwarded monthly to Lakewood, yet claimed that documents over a month old were not produced because they were not at Lakewood.

Hillman repeatedly maintained that its original treatment records were at the LTCs and that copies were forwarded monthly to the Lakewood office. Hillman promised the State survey agency in writing before the April survey visit that it was updating its central files monthly. P. Ex. 2 and HCFA Ex. 10. Thus, Hillman asserted that it supplied "plans of correction, which provided, among other things, that: (i) all current clinical records are maintained at Hillman's offices located in the LTCs in which it treats patients and (ii) all plans of care are approved by physicians who sign the plans of care." Hillman Br. at 5 (citations omitted). Hillman then stated that it "subsequently confirmed," by letter, that "current clinical records are maintained" at the LTCs and "then copied and sent to Hillman's Lakewood billing office on a recurrent basis." Hillman Br. at 3. Further, Hillman stated that its administrator, Dr. Akinrolabu, informed the State surveyor, Mr. End, of "this procedure during the initial surveys." Hillman Br. at 4.

Dr. Akinrolabu's testimony at the hearing similarly asserted repeatedly that the therapists were in fact forwarding copies of their records monthly. Thus, asked what the procedure was for forwarding the records from the LTCs, Dr. Akinrolabu testified that on "a monthly basis when the therapist writes up all the notes and we have to bill the fiscal intermediary, every 30 days, they send us their records either by Express Mail or by regular mail or sometimes we tell them to fax a few things over." Hearing Tr. 198-99 (emphasis added). Similarly, in its appeal letter, Hillman stated that -- [O]riginals of all clinical notes are always available at these [LTC] facilities on a daily basis. However, in order to meet the provisions of Section 405.1722(c) and specifically those of Section 405.1722(f), photocopies of these records are retrieved from these remote locations and kept in the main office of the provider on a monthly basis, with subsequent monthly updates. Hillman Appeal Letter at 3 (emphasis added). The appeal letter further asserted that this was what was promised in the January plan of correction and was consistent with the letter sent by Hillman and accepted by the State agency "to the effect that active patient charts shall be updated in our main office on a recurrent basis." *Id.*

Hillman certainly made numerous representations to HCFA throughout the survey and certification processes that its understanding of its obligations under the regulations and its intended method of fulfilling them involved copying all patient records at the LTCs and forwarding them monthly to the central office. At the January survey, Mr. End found that Hillman was not in compliance with the clinical records COP because it was unable to produce six records of patients treated in the last 30 days. HCFA Post-Hearing Br. at 6-7; HCFA Ex. 4; Hearing Tr. 53-54. Mr. End testified that he told the office manager that "the records must be maintained on site for easy review and that they should be readily accessible" and that "the originals must be kept in nursing homes so we accept copies of the medical records." Hearing Tr. 51-52. By "on site," he said he told her he meant "in the main facility." Hearing Tr. 52-53.

Hillman was given 45 days to achieve compliance with the five COPs for which it was cited, and submitted a plan to do so. The State agency required that plan to be supplemented by a letter to correct the absence of patient records at the main facility in Lakewood. Hearing Tr. 60-66. At the follow-up survey in February, the other COPs were found to be corrected but no patient records were available for review. Mr. End testified (and Mr. Kozek, his superior, confirmed) that they decided to give Hillman "a break" or the "benefit of the doubt" and find compliance since it had corrected four of five violations. Hearing Tr. 69, 169-70. The premise of this decision was (1) that Hillman would provide written assurance that "records would from then on be maintained on site," and (2) that the surveyors would "return in the near future to do a record review." *Id.* The Hillman letter containing the requisite commitment was referenced above. HCFA Ex. 10; P. Ex. 2. Hillman gave no notice to the State survey agency of its inability to meet this commitment.

The ALJ focused his analysis on Hillman's argument disputing the reasonableness of interpreting the clinical records COP to require central filing of contemporaneous copies of all records in its main office. The ALJ found HCFA's interpretation unreasonable. He concluded that the evidence did not establish that Hillman promised to maintain contemporaneous copies, but "proves at most that Petitioner promised that it would maintain such records at its Lakewood office, updated at 30-day intervals." ALJ Decision at 14. It is, in fact, undisputed that Hillman did so promise, and we therefore adopt an FFCL to that effect as set forth at the end of this decision. The ALJ failed to examine the records actually produced by Hillman, in light of Hillman's promise. Such an examination supports an inference that either (1) Hillman failed to fulfill this promise, or (2) the documents produced at the April 5th survey were the product of the monthly updating which Hillman both promised and claimed to have instituted, and they show wholly inadequate record-keeping.

HCFA denied that it ever asserted a requirement that "contemporaneous" copies be centralized and further denied that the issue was material to the case since Hillman's participation was not terminated for failure to keep centralized copies of its files but only because the records in fact produced by Hillman (from wherever located) showed noncompliance. The ALJ found that HCFA's purported requirement of contemporaneous central copies was "central to HCFA's case" that Hillman's exhibits were not "relevant" because they were not present at the central office on April 5th. ALJ Decision at 9-10. The ALJ went on to reject the contemporaneous central filing requirement, because the Act and regulations contain no such express requirement, "so long as the provider is able to access the records, and to retrieve information in those records, or copies of them, promptly when necessary." ALJ Decision at 10. The ALJ concluded that this interpretation meant that the records provided by Hillman as exhibits were relevant even though not provided to the surveyor in April.

The conclusion that Hillman's exhibits are relevant and should be the sole basis of assessing Hillman's compliance does not follow from the interpretation of the regulation not to require contemporaneous centralized copies, for several reasons: Hillman was not faulted for failing to produce "contemporaneous" copies, but for failing to have required records readily accessible and for having records without timely physician signatures for service periods generally one to three months earlier. Hillman had expressly promised to keep central files updated monthly and repeatedly indicated that it had done so, as part of addressing an already identified deficiency in its ability to fulfill its obligations to monitor its therapists' work and to evaluate its performance, as required by 42 C.F.R. 405.1726. Therefore, the records produced on the survey date should have been complete at least as of the preceding month and were not.

The ALJ agreed with HCFA, as do we, that the regulations do require that records be maintained "in a way that enables a surveyor to have access to them" upon request at a provider's central office. ALJ Decision at 12-13. Thus, Hillman should have been required to show that it was able to produce the documents on request even if housed elsewhere, even under the ALJ's interpretation of the regulation, whether through faxing or physical retrieval, or other means. (We note that the record established that Hillman did have available facsimile transmission equipment for this purpose).

The facts established by HCFA give rise to an inference that the records produced in response to the survey represented the records in fact readily accessible on the day of the survey and that more complete files produced many months later for the hearing are not relevant to represent the state of Hillman's clinical records on April 5, 1995. The burden was on Hillman to negate this inference by probative evidence establishing that its exhibits represented a more accurate measure of the state of its records as of the survey date.

2) The alternative explanation that only a subset of "billing" records was requested and other available documents were not provided is inconsistent with the record evidence.

To counter the above-described inference, Hillman asserted that complete clinical records were not actually requested at the survey, but rather only "billing" records were requested. This assertion appears inconsistent with Hillman's arguments about off-site filing. Hillman's argument is that Dr. Akinrolabu showed Mr. End the files where Hillman kept the monthly updated clinical files, in accordance with its promise, and Mr. End was allegedly satisfied merely to observe the filing cabinets and made no requests for records. See Hearing Tr. 215. The request for records made by the Aetna representative, Mr. Livesay, was allegedly directed only at "billing" records. Thus, Hillman contended, the complete records were not provided because of the limited nature of the request. This theory appears to imply that Dr. Akinrolabu was asserting to Mr. End by his actions (i.e., showing him where the updated central files were being kept) that the promise of monthly updating was being fulfilled, which would make the initial filing of clinical records off-site irrelevant to Hillman's defense to its failure to produce adequate records. In other words, Hillman here was saying that it produced incomplete records, even though complete records were available, not because they were off-site, but because only a subset of records was requested.

Hillman asserted that this distinction between its billing records and its clinical records was central to its case because Dr. Akinrolabu believed that Mr. Livesay was requesting only billing files. See, e.g., Oral Argument Tr. 102. Yet, Hillman failed to produce consistent testimony supporting either the existence of such a distinction in its record-keeping system or the specific request for such narrow document production by either surveyor. Thus, Hillman did not provide testimony from any staff at Hillman that a practice of dividing clinical and billing records predated the survey nor offer any documentation, such as a staff manual or instructions to the therapists, explaining which records were to be transmitted for or maintained in a billing file, as opposed to the clinical file. Dr. Akinrolabu stated that the difference between "billing files" and clinical files was that instead of creating a "third copy" of the clinical records (besides the original and therapists' copies in the satellite LTC offices) -- [W]e said, "Okay. We need only a number of things for billing." For example, we want to be sure that we have the patient's information, which is the Patient Information Sheet, a copy of the evaluation, and then in this same file we keep the UB 92 [sic], we keep letters for coinsurance . . . and that's -- as the "Billing File," because that's what the billing person needs information from to do her billing. Hearing Tr. 212-13. But as noted elsewhere, his descriptions of the documents forwarded by therapists to the central office, both in the letters submitted to the state agency and in testimony and briefing elsewhere, show no consistent support for the idea that the therapists identified such a limited subset of documents to forward.

Most significantly, this description is wholly inconsistent with what was in fact produced on April 5, 1995. The files provided to the surveyors did not include the named items (such as UB-82's or coinsurance papers) and did include clinical records such as patient plans of progress, physician treatment orders (as well as evaluations), and discharge summaries. See, e.g., HCFA Exs. 20 and 22. As HCFA pointed out, neither party's exhibits contain documents purporting to be coinsurance records or UB-82's. HCFA Reply Br. at 37. If Hillman's position were correct, the UB-82's ought to be in HCFA's exhibits, since, according to Hillman, those represent the "billing files" for which it said Mr. Livesay was looking. There was no claim that HCFA's exhibits were not a full set of the documents produced by Hillman at the April survey, and Hillman did not assert that UB-82's appear in the record or otherwise respond to this point.

Further, Dr. Akinrolabu's descriptions of the scope of the surveyors' document requests were inconsistent. For example, he initially said that Mr. Livesay asked for UB-

82s, coinsurance documents, and "to see the -- admission that was -- as authorized by the physician." Hearing Tr. 213. To see the physician authorizations for treatment would mean reviewing the very kind of records for which Mr. End was looking, i.e., clinical records. See HCFA Reply Br. at 38-39. Dr. Akinrolabu later testified that Mr. Livesay "didn't ask me for physician signatures. He wanted to see the initial evaluation. It was later on that they said, Well, some of them did not have physician signatures' and we explained it to him. He said, Fine.'" Hearing Tr. 238. Thus, Dr. Akinrolabu acknowledged that Mr. Livesay did seek treatment records containing physician authorizations.

A further difficulty which HCFA pointed out with the alleged distinction between billing and clinical records is that it does not exist in the law, but only, if at all, in Hillman's own characterizations. HCFA Reply Br. at 38, n.33. The Act and the COPs refer only to clinical records. If this distinction is not one in general use and was never explicitly communicated to the State survey agency prior to the survey, it is less plausible for Hillman to say that the reason it did not produce all the records then in its possession (regardless of where they were located) for the patients about whom the surveyors inquired is that only billing records were requested. Mr. End specifically testified that he requested complete clinical records and that he was not told that Hillman maintained "separate files, in other words, a billing file as well as a patient-care file." Hearing Tr. 73, 124, 128. Had such a distinction been clearly communicated, there might conceivably be some basis to accept that Mr. End should have known that a request for documents as part of a fiscal review might result in records from the limited billing file, and that he should have followed up by requesting the clinical files. However, if, as appears from the record here, he knew only that the files might be at different locations, then he had no reason to think that if he got files for a patient at all, they might consist of only a separate billing file rather than clinical records, especially where the files that he did get included clinical documents. Furthermore, if it was not reasonable to expect Mr. End or Mr. Livesay to be aware of the purported filing distinction, this undercuts the likelihood that Dr. Akinrolabu did in fact think that the document request was intended to be limited based on that distinction.

Hillman elaborated on appeal on this explanation that the request was too narrow to include completed clinical records by suggesting that Aetna sought only billing documents from very specific time frames. To this end, Hillman relied on a computerized list of claims and on documents showing claims denied by service dates. Hillman described the computer print-out as "the actual list presented by Aetna" at the April 5, 1995 survey. Analysis by Petitioner at 2-3, and annexed list. HCFA argued that the list does not demonstrate that Aetna's document request at the survey was limited only to patient records from those time periods, or that the records for those time periods need not be complete. HCFA Reply Memorandum at 6. Further, HCFA argued that Mr. End, in any case, asked for complete patient records, and that the documents received by Mr. End included ones outside the time periods in the list. *Id.* at 7.

Even assuming that Mr. Livesay presented the list to identify the service dates of patient claims about which he wanted to review the documentation, and even assuming that Dr. Akinrolabu did not understand Mr. End to be making a broader request for documents than Mr. Livesay, that would not mean that Hillman was asked to produce only records dating from the particular services dates. Records from other periods would be relevant to the extent they were necessary to support the allowability of the claims for that period. Thus, in order to substantiate its claim to payment for the treatment provided during the specified service dates, Hillman would have had to provide evidence that required certification and/or recertifications were obtained to support the medical necessity and appropriateness of the treatment, and that the treatments were provided under a plan of care which was reviewed within the required time frame, even if the documentation was dated outside the service date period. Furthermore, on April 5th, Hillman clearly understood the request as broader than what it later contended; the documents provided at the survey included many documents dated prior to the listed service dates. See, e.g., HCFA Exs. 18, 20, 30, and 34.

Similarly, while the claims denial records included with Hillman's patient record exhibits (and the beneficiary on-site worksheets included with HCFA's patient record exhibits) support Hillman to the extent that they suggest that the records Aetna requested for each beneficiary were related to a particular service period, they do not support Hillman's position that this meant it was asked to produce records only from that period. For example, records showing a plan of care, physician's order, or certification prepared prior to the immediate service period would be relevant to responding to many of the items reflected on the review worksheets and listed as a basis for claims denial. For example, a plan of care which simply continues a plan from an earlier period could only be reviewed by providing the earlier plan specifying the amount, duration, and scope of services. The claim denial records, in many cases, show reasons for denials that reference the absence of documents that would not necessarily be dated within the time period, such as physician certifications and initial orders for treatment, but which would be relevant to support claims for the service period treatments. See, e.g., P. Ex. 14, at 8; P. Ex. 27, at 12.

3) Intrinsic evidence undercuts the reliability of Hillman's exhibits.

The ALJ concluded, based on examination of Hillman's exhibits, that they appear on their face to be what they purport to be -- authentic complete treatment records of the patients at issue. ALJ Decision at 18. The problem is that Hillman asserted only that these were records maintained at the LTCs. Hillman did not expressly assert that its exhibits constituted an accurate representation of the state of its files at the time of the April survey, nor did it even explain at what point the records which it submitted were gathered and copied nor when signatures absent on HCFA's corresponding documents were added to those produced by Hillman. Even assuming Hillman's exhibits were authentic treatment records maintained at the LTCs, this fact would not suffice to show that they were relevant. The issue is not whether these exhibits are copies of authentic clinical records - - but whether they are clinical records that existed in their present form at the LTCs on April 5, 1995, were readily accessible, and would have been produced at the survey, if requested. Only based on these premises are they relevant for the purpose for which they were offered, i.e., as evidence of Hillman's state of compliance with the Medicare COPs as of the time of the April 5th survey. The ALJ Decision does not examine the exhibits in light of these additional implied claims.

Accordingly, the exhibits are on their face unreliable to show compliance. If offered for the proposition that physicians did timely review plans of care, Hillman's exhibits are insufficient. Physicians' signatures on plans of care for services provided in January or February that are dated weeks late or even after the survey date evidence late review, not timely review, and tend to support HCFA's findings rather than to rebut them. See, e.g., P. Ex. 9, at 3, 8. Other of Hillman's exhibits merely show (assuming the authenticity of the physicians' signatures) that physicians ultimately signed the plans of care, but show nothing about whether they were signed as of the survey date. See, e.g., P. Exs. 12, 17, 18, 20, 28. Hillman argued that physicians may have signed the forms in a timely fashion, but simply neglected to fill in dates or relied on dates elsewhere. However, this contention is unsupportable on the evidence here. Absent dating of the signatures or other evidence clearly showing that the physician reviews were timely, we do not find support in the record to rely on Hillman's exhibits as evidence of its compliance at the relevant time, for several reasons.

As noted, the few physician signatures which were dated were in some cases dated substantially more than 14 days after the order or review which they approved, undercutting any assumption that physicians' signatures implied timely review. As discussed above, Hillman did not offer a sufficient explanation for why it would not have produced the completed versions of the documents at issue earlier, if they were in fact available (either at the LTCs or in a separate "clinical file"), when the incomplete versions were themselves produced as responsive to the April document requests. Even if the therapists did not routinely update the central office files with completed copies of their records, despite Hillman's promises to do so after the earlier surveys, if Dr. Akinrolabu understood the surveyors' requests sufficiently to produce these records at all, he should certainly have understood that the most complete version of a specific form should be provided. Hillman failed to produce a single physician to identify a signature, to explain adequately how signatures came to appear on Hillman's exhibits but not HCFA's, or to testify about the practices of attending physicians in regard to signing and dating reviews.

Dr. Akinrolabu, even if a credible witness, did not state that he had personal knowledge that physicians' signatures had been obtained in a timely manner, or that the records in the LTCs had been completed in a timely manner. In fact, he testified that he had "no way of knowing exactly what date" a physician signed a particular record "[i]f it's not dated." Hearing Tr. 236. This statement underscores the importance of physicians dating their signatures. The rehabilitation agency is responsible for supervising treatment and assuring compliance with Medicare requirements, and performance of its oversight duties depends on an accurate and complete clinical record to allow it to verify that physician review is being performed timely. Hillman presented no testimony from any witness with personal knowledge of the preparation of the clinical records at issue or the conduct of the physicians' reviews, such as therapists or LTC staff. Many of the forms (e.g., progress reviews) have multiple entries dated over a significant period of time, so that it is clear that they were not filled out on a single date. Therefore, it would be unreasonable to infer that an undated signature should be associated with any particular date on the form, rather than with another. The forms in most instances have an express request for a date immediately next to the physician signature request, e.g. a single line with the words "physician's signature and date" imprinted underneath. See, e.g., P. Ex. 18, at 3. Thus, the physicians had reason to know that their signatures should have been accompanied by a date. The other professionals who signed these records, such as nurses and therapists, generally did date their signatures in the appropriate spaces on the forms.

Many of the forms produced at the survey, which had apparently been copied and forwarded to the central office before the physicians signed them, already contained dated signatures by therapists, so it cannot reasonably be assumed that physicians routinely affixed their signatures on the same day as the therapists. Consequently, it is clear that physicians could not have been relying in most cases on the dates affixed by therapists as an accurate statement of when the physicians signed the documents. Even if physicians intended to rely on some other date on the form, such a practice would make it impossible for the rehabilitation agency to meet its oversight responsibilities in assuring that the physicians were performing timely reviews, since no inference can be drawn as to which date on the form is the date on which the physician signed it. Thus, while Hillman's exhibits might be "relevant" in a general sense, they are clearly inadequate by themselves to show compliance with either of the COPs at issue here. The ALJ's conclusion that Hillman's patient record exhibits are the best evidence of its compliance with the Medicare COPs is not supported by substantial evidence on the record as a whole. Cf. ALJ Decision at 16.

C. The factors cited by the ALJ in accepting Hillman's version of survey events are not supported by substantial evidence or based on reasonable inferences, and other relevant factors were disregarded without adequate explanation.

The ALJ rejected the surveyor's testimony as a basis for concluding that HCFA's exhibits represent all of the treatment records for the patients at issue maintained by Hillman and readily accessible on the date of the April 5th survey. Instead, he accepted Dr. Akinrolabu's assertions that other treatment records existed then but were not produced because the surveyor failed properly to request them. The ALJ's consideration of the exhibits produced by

Hillman as relevant to the state of Hillman's records on the date of the survey is entirely founded on the credence which he gave to Hillman's version of survey events. 34/ We conclude below that, in weighing the competing versions, the ALJ erred in not assigning to Hillman the burden of proof even in regard to the affirmative claims which it made concerning the inadequacy of the survey process and how Hillman was affected by any such inadequacy.

Further, in considering the testimony, the ALJ expressly did "not find from the demeanor of either witness that the witness was not credible." ALJ Decision at 18. Instead, the ALJ evaluated credibility by measuring each version of events "against whatever facts are in evidence that supports or contradicts it," thus emphasizing the believability of the accounts rather than that of the witnesses. *Id.* Below, we find that none of the cited facts is adequately supported by the record and that together they do not suffice to show by a preponderance of the evidence that Dr. Akinrolabu's account of events is more believable.

1) Hillman's claim that it did not produce complete clinical records at the survey because the surveyors requested only limited billing records is an affirmative argument for which Hillman had both the burden of coming forward and the burden of persuasion.

Hillman's assertions that the records it produced at the survey were incomplete because of the inadequacy of the surveyors' document requests constitute a challenge to the procedural regularity of the survey and is therefore in the nature of an affirmative argument. The ALJ recognized that the petitioner has the burden of proving such an argument. See Prehearing Order at 3. As part of that burden, Hillman was required to show that it was prejudiced by any procedural failure. Under the circumstances here, this meant at a minimum that Hillman would have to show that the records requested by Aetna and produced on April 5th were different from the records that would have been produced if the surveyor had made clear that he was requesting all of the treatment records that were maintained and readily accessible on that date for the patients at issue. Thus, even were Dr. Akinrolabu's account of the survey events credible, that alone would not suffice to establish that Hillman's exhibits were reliable as evidence of its compliance on April 5th.

2) The ALJ's reasons for finding Hillman's account of the events plausible are not sufficient on the record and do not address other relevant facts.

The ALJ relied on three factual findings to conclude that Dr. Akinrolabu's account of the events was more believable: (1) that the primary purpose of the April 5th visit was a billing record review; (2) that Mr. End's testimony that documents were faxed into Lakewood that day was not credible; and (3) that Hillman's exhibits are "on their face" consistent with what they purport to be. ALJ Decision at 18. We discuss each of these findings below and then discuss other factors which the ALJ disregarded.

a) Primary purpose

The first finding was that the "primary purpose" of the April survey was "not to conduct a Medicare compliance survey, but to review Petitioner's billing records to satisfy questions raised by the Medicare intermediary." ALJ Decision at 18. The ALJ stated that Mr. End and Dr. Akinrolabu agreed on this one point. *Id.* Yet, the ALJ cited to no testimony by Mr. End to the effect that the primary purpose of the visit was a claims inquiry and not a follow-up to the earlier Medicare compliance survey, and we have found no such testimony in the transcript. The April visit, according to both Mr. End and Mr. Kozek, his supervisor, was conducted to perform the planned follow-up to the promises Hillman made after the February revisit and was timed partly to take advantage of the "opportune" circumstance that Aetna was interested in doing joint targeted surveys of several rehabilitation agencies with billing problems. Hearing Tr. 71, 170-71. Mr. End testified that the April survey was "specifically to inspect for the condition of clinical records." Hearing Tr. 71. Mr. Kozek testified that the State survey agency was focusing on "looking at clinical records" and would have sent Mr. End for this purpose within several months of the February survey even if Aetna had not become involved. Hearing Tr. 171, 179. This testimony is not consistent with characterizing Mr. End as in agreement that Aetna's claim inquiry was the "primary purpose" of the joint visit.

In any case, the ALJ gave no reason why it would be relevant what the "primary" purpose of the survey was, if it were evident that a follow-up records review for Medicare compliance was an additional purpose of the visit. Hillman pointed to no authority by which it could disregard record review obligations to Medicare based on the relative primacy of the purpose of visits by two surveyors. Hillman had obligations both to Aetna as its fiscal intermediary and to the State survey agency.

Regarding the purpose of the visit, the ALJ stated that Mr. Livesay brought the patient list and that he was persuaded that therefore the most likely documents to have been sought were "records related to Petitioner's reimbursement claims." ALJ Decision at 19. Even if Dr. Akinrolabu perceived, and perceived correctly, that Aetna's representative was the more active in presenting the document requests or selecting particular patients to be the subject of review, Dr. Akinrolabu could not reasonably assume under the circumstances that Mr. End was merely a disinterested observer. Mr. End's presence implied that he had some independent purpose in visiting, and the context of the prior surveys should have alerted a reasonable provider that that purpose was likely related to a records survey. Thus, the ALJ should have considered that this joint visit did not occur in a vacuum, but after two prior survey visits and follow-up correspondence all touching on the inadequacy of Hillman's available records.

The ALJ further disregarded evidence that the interests of the two surveyors in reviewing Hillman's records were sufficiently co-extensive that it was not necessary for Mr. End to assert a different document request. The evidence suggests that the records relating to reimbursement claims would be expected to include the same documentation the absence of which caused Mr. End to find deficiencies. The regulatory requirements for claims reimbursement are very similar in their physician certification requirements to the participation provisions evidencing physician involvement in ordering and reviewing care. The claims denial forms reference the absence of physician orders, physician certifications, and other items that would be in clinical records. Consequently, it is difficult to see what sort of billing records would support the legitimacy of a claim without containing most of the same information that would be required in clinical records showing physician involvement as required by the two COPs.

As noted above, the conclusion that Mr. Livesay and Mr. End both sought clinical records is consistent with the observation that the documents actually produced, while incomplete in terms of demonstrating adequate and timely physician review, consisted of clinical treatment records, not the purported "billing file" described by Dr.

Akinrolabu. We note that in its appeal letter, Hillman stated that the Aetna surveyor requested "the charts" of patients for review, and that the state agency surveyor "did ask to see the location of current clinical charts" to verify the central filing promised in February. Hillman Appeal Letter at 4. This supports the conclusion that both surveyors were interested in the same documents (even if Mr. End did not ask for the records himself) and further undercuts any claim that there was a difference between patient charts or clinical records and a limited billing file.

b) Faxing documents

The second finding was that the ALJ did not believe "Mr. End's testimony that Petitioner faxed documents to its Lakewood office" on the survey date. ALJ Decision at 18. The ALJ did not believe that the documents were faxed because the exhibits submitted by HCFA do not contain fax imprints and because Mr. End "admitted" not personally witnessing any document being faxed. Mr. End testified that on April 5, 1995 he met with Dr. Akinrolabu and asked for the records of the listed patients and further requested "to go to the files and observe these records while they were being pulled." Hearing Tr. 72. He testified, however, that when they went to the files, the records were not available and "had to be faxed in over a period of approximately two hours -- two to three hours from nursing homes across the state." *Id.* at 73; see also *Id.* at 85, 89, 93, 97-98 (additional references to faxing). On cross-examination, Mr. End testified that he did not actually see the documents coming in on a fax machine but "was told they had to be faxed." Hearing Tr. 119-20.

Apparently, because Mr. End explained only on cross- examination that he was basing his belief that documents were being faxed on Dr. Akinrolabu's statement to him to that effect, the ALJ characterized this explanation as an admission. The ALJ ignored the fact, however, that this statement also constituted an uncontradicted assertion. Dr. Akinrolabu did not deny that the surveyor was kept waiting for two or three hours and, while he denied that documents were faxed in, he never directly denied that the surveyor was either directly or indirectly led to believe that they were. Dr. Akinrolabu did acknowledge that the Lakewood office and the LTC satellite offices had fax machines, and the LTC offices sometimes faxed in records. Hearing Tr. 216. Thus, Mr. End presented a reasonable basis for his assumption that the documents were being faxed and, if he proved misled in this regard, it does not undercut his credibility. The ALJ does not explain why Mr. End would have any motive to lie about he understood or what Dr. Akinrolabu told him about faxing documents, nor did Mr. End at any point make an inconsistent claim to have personal knowledge of the faxing. Therefore, even assuming the documents were not faxed, this would not undercut Mr. End's credibility.

We note that it is not important to HCFA's case that any of these documents have been faxed. To the contrary, the fact that Hillman had available the means to make those documents available even if they were housed off-site means that Hillman's production of incomplete records raises questions regarding what records Hillman had readily accessible and when the records were completed.

c) The appearance of the records on their face

The third finding was that Hillman's exhibits "are consistent with what Petitioner purports them to be, which is complete treatment records of the 20 patients" at issue. As discussed above, while the documents appear on their face to be patient treatment records, nothing in their appearance gives any assurance that they are complete treatment records as of April 5, 1995. The ALJ was also impressed, in relying on Hillman's documents as credible, by the appearance on Hillman's records of signatures of "numerous individuals" as suggesting genuine rather than fabricated documents. ALJ Decision at 19. However, this reliance overlooks the fact that what is disputed is not the genuineness of the numerous signatures of nurses and physical therapists. It is perfectly possible for physicians' signatures to have been added (by the physicians or others) to otherwise complete and genuine treatment records long after the fact and such an alteration would not necessarily show any obvious indicia of fabrication. At least one file, for example, has signatures added to January records but dated April 20 (after the survey). Clearly, this physician was asked or permitted to complete the record months late, and one could infer that perhaps others of the undated added physicians' signatures might also have been obtained long after the fact. See P. Ex. 9, at 2 and 8; HCFA Ex. 26. The reasonableness of such an inference is buttressed by the fact that many key signatures are undated but appear above lines that call for both a signature and a date.

d) Other factors disregarded by the ALJ

The ALJ failed to address record evidence that appears to conflict with his conclusion about the credibility of the two accounts of the survey or to explain why he did not credit such conflicting evidence. Thus, the ALJ did not address evidence that Hillman's only witness was Hillman's administrator and co-owner and therefore had himself much at stake in the outcome of the testimony. See Hearing Tr. 194. While the surveyor could conceivably have some interest in being seen as having done his job adequately, the ALJ did not explain why he did not consider in evaluating the credibility of the witnesses' accounts whether the degree of self-interest which might impact Dr. Akinrolabu's memory or description of events was disproportionately greater, making his uncorroborated testimony at least somewhat less reliable.

In addition, the ALJ erred in stating that no witness corroborated the testimony of either Mr. End or Dr. Akinrolabu. ALJ Decision at 18. Neither party produced a second eyewitness to support its account of events at Hillman's office on April 5, 1995. However, Mr. End's supervisor did testify and corroborate some important elements of Mr. End's testimony about the timing and purpose of the several surveys. See Hearing Tr. 159, 164. Thus, Mr. Kozek testified that Mr. End was sent to Hillman on April 5, 1995 with the intention of following up on whether Hillman had achieved compliance in accordance with its commitments after the February survey, which makes it more likely that Mr. End was at Hillman actively seeking to determine whether its records were in compliance rather than merely serving as a companion to Mr. Livesay. Mr. Kozek's testimony also provided support in that his testimony shows that Mr. End's contemporaneous accounts of his visits to Hillman were consistent with his later testimony.

Furthermore, the ALJ specifically faulted HCFA for failing to produce a statement or testimony from the Aetna surveyor to support Mr. End. ALJ Decision at 17, n.10. However, Hillman was the proponent of the proposition that a billing inquiry had been made for which only limited records were needed, rather than a request to survey patient clinical records. Despite clearly having the burden to support its proposition, Hillman not only failed to produce Mr. Livesay to explain the scope of his inquiry but objected to any testimony from Mr. End on this topic and offered no testimony from the individuals presumably under its control who worked with Dr. Akinrolabu to produce the records on April 5 (who could have at least addressed what their understanding was of what they were asked to produce).

Finally, the documentary record includes with each of HCFA's patient record exhibits a form entitled Beneficiary On-Site File Review Worksheet (mentioned above) with a date entry of April 5, 1997 on each one. Hillman did not challenge the authenticity of these documents. The record is not clear on whether these documents were prepared by Mr. End or Mr. Livesay (although the latter seems more likely in light of the title reference to beneficiaries and HCFA asserted on appeal that they were Aetna forms). The record also does not indicate whether these forms were filled in during the survey at Hillman's offices or later. Even in the absence of more information about the preparation of these documents, the ALJ should have considered them as contemporaneous written evidence of the scope of what was requested. The worksheets generally support Mr. End's testimony that the information Aetna was seeking would have required the same kind of documentation as he was seeking, since they include entries for whether the file includes a "physician's written order for the service," whether the plan of care was complete and "signed by the physician prior to" billing, and whether the medical necessity of the plan of care was "recertified by the physician on a timely basis," i.e., "every 30 days; prior to billing." See, e.g., HCFA Ex. 23, at 1.

D. Noncompliance with the physician involvement and plan of care condition of participation

An essential part of the Medicare scheme for OPT services is that physicians provide oversight to assure that the care provided is appropriate and necessary for the patients' conditions. The parties disputed at what point the oversight provisions require physicians to review plans of care established by PTs. In this section, we explain our conclusions on the interpretation of these provisions and discuss how to analyze the evidence of compliance and of the nature of the deficiencies in light of these conclusions. The Act permits payment for OPT services only for a beneficiary, who is "under the care of a physician" and -- with respect to whom a plan prescribing the type, amount and duration of physical therapy services that are to be furnished . . . has been established by a physician . . . or by a qualified physical therapist and is periodically reviewed by a physician.

Section 1861(p) of the Act. This section should be read together with section 1835(a)(2)(C) which permits payment for OPT services only if a physician certifies (and recertifies as required by regulations) that the services are needed, that "a plan for furnishing such services has been established" by the physician or therapist, and that the plan "is periodically reviewed by a physician." The regulations require that a written plan of care be established by either a physician or a PT, and that -- The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires . . . . (For Medicare patients, the plan must be reviewed by a physician in accordance with 424.25(e) of this chapter.) 42 C.F.R. 405.1717(b)(3). The reference to section 424.25(e) is mistaken as that section was superseded by section 410.61(e) in the regulations on Medicare Part B benefits. The latter provides that OPT services must be furnished under a written plan of treatment established before treatment by a physician or PT, and must prescribe the "type, amount, frequency, and duration" of services. 42 C.F.R. 410.61(a) - (c). The physician must review the plan "as often as the individual's condition requires, but at least every 30 days" and each "review is dated and signed by the physician who performs it." 42 C.F.R. 410.61(e)(emphasis added).

HCFA argued that these provisions, read together, require that a physician review the plan of care at the outset of treatment. Hillman argued that a physician was required to do a review of the plan of care within the first 30 days (if treatment extended beyond 30 days). HCFA Br. at 59; HCFA Post-Hearing Br. at 35-37; Hillman Br. 27-31. The ALJ concluded that (1) HCFA's interpretation of this regulation was unreasonable; (2) even if he accepted HCFA's interpretation, the weight of the evidence would not show a violation; and (3) HCFA did not prove that the asserted violation would be a condition-level deficiency. ALJ Decision at 19-20.

The ALJ characterized HCFA as requiring physicians to "approve the details" of the plan "before therapy is initiated," and he found this interpretation inconsistent with the statutory and regulatory language, which he read as allowing the PT to plan and initiate care subject to a physician review within 30 days. *Id.* at 20-22. The ALJ also concluded, and Hillman did not contest, that the Act "mandates that physical therapy be ordered by a physician." ALJ Decision at 20-21. The ALJ further concluded, and HCFA did not contest before us, that such physician approval for treatment could be evidenced by either a signed order for OPT or a physician signature on the initial plan of care. ALJ Decision at 22; HCFA Br. at 72, n.35. HCFA contended that its interpretation was supported by a review of the Medicare payment regulations and that the ALJ erred in considering the plan of care COP in isolation from the overall legal scheme regulating providers. HCFA Br. at 55, 57-58. The conditions for payment of OPT services require (in relevant part) certification by a physician that the services were needed, were furnished "under the care of a physician" and were provided "under a plan of treatment that meets the requirements of 424.25." 42 C.F.R. 424.24(b) and (c)(ii) and (iii). This certification by the physician must "be obtained at the time the plan of treatment is established, or as soon thereafter as possible" from either the physician who established the plan or (if a therapist established the plan) a physician who has knowledge of the case. 42 C.F.R. 424.24(c)(2) and (3). In addition, the physician must recertify the continuing need for OPT services "at least every 30 days." 42 C.F.R. 424.24(c)(4). HCFA argued that this language ties together the plan of care requirements and the certification requirements in a way that contemplates a physician review near the time of the establishment of the plan of care, as well as a 30-day review period thereafter. (HCFA denied that it interpreted the regulations to require the review before any treatment, as the ALJ suggested.)

HCFA contended that HCFA Action Transmittal No. 57 (May 1985) (AT-57) also supported this reading. HCFA Br. 58- 59; P. Ex. 8, at 4. AT-57 noted that therapists were permitted to establish plans of care, but stated that a plan established by a therapist must be periodically reviewed and signed by a physician at least every 30 days. AT-57 stated that the same physician reviewing the plan of care should do the certification, at or near the time the plan of care is established, and that recertification should be obtained at the same time the plan is reviewed since the interval of 30 days is the same and the same physician who reviews the plan should recertify. *Id.* HCFA reasoned that if the same physician who did the review is going to certify the need near the time of establishing the plan, it follows that a review is assumed to be taking place about the same time as the certification (i.e., at the beginning of care). HCFA Post-Hearing Br. at 35-36.

Further, HCFA argued that logic suggested that the 30-day review had to have a starting date in an initial review where the physician did not establish the plan initially. HCFA Post-Hearing Br. at 35. Pragmatically, HCFA asserted that the importance of an early review of the plan of care is to assure that it is in accord with the physician's order for treatment and that a patient does not receive weeks of inappropriate care waiting for a physician's review. HCFA Post-Hearing Br. 36. Upon review of the relevant provisions, we conclude that since the physician is required to certify that a treatment plan setting out the type, amount, frequency, and duration of services has been established, it follows that the physician must either have established the plan or have been made aware of the plan established by the PT. It does not necessarily follow, however, that all documents setting out a plan (even those that merely provide more detail than the physician's order) must be reviewed and signed by the physician. Such an interpretation is not evident on the face of the Act or regulations, nor was it communicated adequately in the action transmittal.

As the ALJ noted, the regulations contain no express language requiring physicians to review and sign the detailed contents of a plan of care developed by a PT before treatment is begun. ALJ Decision at 21-22. The ALJ's conclusion that a plan of care developed by a therapist based on the order of the physician must be reviewed by the physician and approved in writing but that review may take place at any point within 30 days of the inception of treatment is not unreasonable and is consistent with the plain language of the Act and regulations. *Id.* This interpretation is only reasonably applied, however, where a physician's order sets forth the type, amount, frequency, and duration of services ordered so that one can reasonably conclude that the services being provided are those for which the physician certified the need and that at the time of the physician's order, the type, amount, frequency, and duration of services had been planned. The AT-57 provisions are met if the reviewing physician met the certification requirements, and if recertification is obtained whenever the plan is reviewed in the ensuing 30-day interval.

HCFA's position that the physician should review any initial plan of care documents developed by a therapist (and so indicate by signing and dating the document) is a reasonable one, since it would provide assurance that the plan of care to which the physician certified was the plan of care that the therapist would implement, and would facilitate monitoring the 30-day review and recertification requirements. Contrary to what HCFA argued, however, it is not necessary to interpret the physician review requirement to mean a signed and dated review at the outset of care in order to have a "starting point" to calculate 30-day intervals (in fact, "outset" is a somewhat vague concept). Hillman could have reasonably understood the requirement to mean that physician reviews were required within 30 days of the first treatment or within 30 days of the physician certification, and every 30 days thereafter.

Hillman contended that HCFA, by interpreting the plan of care requirements to require physician involvement at the outset, was seeking to impose a superseded requirement that the plan of care be established by physicians rather than by therapists . See Hillman Br. at 27-29. Thus, Hillman argued that HCFA was trying to rewrite the requirement that a physician or therapist establish a plan of care as if it meant both physician and therapist must establish the plan. *Id.* Hillman characterized HCFA's effort to interpret the timing of physician review of the plan of care in relation to other parts of the Medicare regulations, law or action transmittal as "bootstrapping." *Id.* at 29.

We disagree with this analysis. The statute clearly requires that the physician certify that a plan has been established either by the physician or by the physical therapist, as well as that the services were needed. HCFA's interpretation that this means that the physician should actually review, sign and date the document containing the plan established by a PT is reasonable, perhaps even preferable in providing additional assurance of the appropriateness of the actual care, and does not amount to usurping a physical therapist's ability to design a plan of care. We find simply that it is not the only reasonable interpretation and that Hillman did not have adequate notice.

Even though HCFA argued that we should defer to its interpretation of the regulations to require a physician to review and sign the plan of care at the beginning of treatment, HCFA also argued that even if this interpretation were not accepted, Hillman would be out of compliance with this condition. HCFA argued that many of the files obtained at the survey do not show physicians performing any plan of care reviews at all, either at the outset or after 30 days. HCFA Br. at 70, n.32. A review of HCFA's exhibits supports this conclusion in many cases. See HCFA Exs. 17, 19-21, 23, 26-27, 31-33, 35. 44/ HCFA further argued that 10 out of 20 of the records reviewed at the survey lacked physicians' orders or other certifications for OPT. HCFA Ex. 12, at 2-3; HCFA Br. at 70-73. Given the absence of either initial orders or signed plan of care reviews, we conclude that HCFA established a prima facie case that Hillman was not complying substantially with this COP as of April 5, 1995. Unless Hillman presented evidence sufficient to show the contrary by a preponderance of the evidence, HCFA would prevail on this issue.

Based on its interpretation and using its own set of patient record exhibits, Hillman argued that it had met the 30-day review requirement in virtually every case. In part, Hillman argued that it was in compliance in certain instances, despite the absence of reviews, because most of the patients at issue completed their course of therapy within 30 days (even if they later reentered therapy) and those whose treatment exceeded 30 days had physician reviews in their files in all but one instance (P. Ex. 26). Hillman Br. at 30. Further, Hillman argued that the fact that the vast majority of the relevant physician signatures appearing in its exhibits are undated should not undercut their reliability or timeliness because (1) physicians may have relied on other dates on the documents, and (2) whether physicians signed and dated progress reviews under 42 C.F.R. 410.61(e)(3) is "clearly not an issue subject to challenge here." *Id.*

Even taking as accurate Hillman's representations about the service dates of treatment for the patients about whom Aetna was requesting documents, we would not conclude, for reasons discussed above, that Hillman was asked to provide only documents from within that narrow time frame. As a factual matter, as also discussed above, a careful review of Hillman's documents does not support Hillman's suggestion that the timeliness of physician signatures may be assessed based on other dates on the same pages. As a legal matter, Hillman's contention that HCFA may not raise the question of the timeliness of the physician signatures in Hillman's exhibits is unfounded. HCFA obviously had no reason to discuss the absence of dating of physician signatures in regard to the documents produced at the survey, in light of the fact that they lack physician signatures almost entirely. This does not preclude HCFA from pointing out, in regard to the versions of the patient records proffered as evidence of compliance by Hillman, that they lack dates. Since the regulations expressly require that physician reviews of plans of care be dated, as well as signed, it can be reasonably inferred, at least as to reviews of plans of care, that the absence of a date accompanying a physician's signature makes it less likely that the review occurred within the required 30-day time period. See 42 C.F.R. 410.61(e).

Because its burden of proof may not have been clear, we have determined that Hillman should have an opportunity to proffer evidence which would support its claim that the physicians oversight requirements were met. Absent such evidence being proffered in accord with our instructions to the ALJ, we would find that Hillman's evidence is not sufficient to show that physician reviews were performed when required. The ALJ concluded as to this COP that HCFA had not proved a condition-level deficiency because it had not proved noncompliance. ALJ Decision at 24. The ALJ noted that "the Act and regulations contemplate that a physician will exercise control over the physical therapy that is provided to a beneficiary." *Id.* The record here established that the absence of physician involvement could raise serious risks to the patients. Mr. Kozek testified without contradiction that these patients are a "very vulnerable, at-risk population," with such complications as age, strokes, and broken hips. Hearing Tr. 173. Mr. End testified that some physical therapy treatments may cause harm to patients, absent physician oversight. Hearing Tr. 46, 91, 108-09. Clearly, Congress and the Secretary anticipated that physical therapy for such beneficiaries had risks sufficient to require active and timely involvement by physicians in approving and monitoring the care, even if PTs may develop the plans of care.

We conclude that the documents produced at the survey so wholly lack documentation of physician oversight as to amount to a condition-level deficiency, absent other reliable evidence of the requisite physician involvement. Hillman's exhibits are not by themselves reliable evidence of such involvement, for reasons discussed above. Should Hillman proffer and present additional reliable evidence, the ALJ should review the evidence as to the level of the deficiency based on the record as a whole at that point.

E. Noncompliance with the clinical records condition of participation

The Act requires OPT agencies to maintain "clinical records on all patients" and the regulations specify that the OPT agency must maintain "clinical records on all patients in accordance with accepted professional standards, and practices," which must be "completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information." 42 C.F.R. 405.1722. The standard on completion of records under this condition provides as follows: Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician's entries into the clinical records are signed by the appropriate physician. 42 C.F.R. 405.1722(c).

The ALJ concluded that HCFA proved that Hillman failed to comply "in some respects" with the standard requiring prompt completion of clinical records, but that this failure did not rise to a condition-level deficiency because there was not a pattern of failure. 45/ ALJ Decision at 25. The ALJ characterized HCFA as interpreting the clinical records COP as (1) implicitly requiring maintenance of "contemporaneous copies" of treatment records at a central location and (2) requiring prompt completion of records, with "prompt" meaning required signatures must be added within 14 days of generation of a record. *Id.* at 25-26. The ALJ rejected the first implicit requirement. As discussed elsewhere, we do not agree that HCFA was requiring contemporaneous copies or that the violation alleged of the clinical records COP depended on location, as opposed to the unavailability, of the files. Based on the records provided at the survey, Hillman clearly did not have readily accessible clinical records which were completely and accurately documented. We therefore conclude that HCFA established a prima facie case that Hillman was not complying substantially with this COP as of April 5, 1995. Unless Hillman presented evidence sufficient to show the contrary by a preponderance of the evidence, HCFA would prevail on this issue.

We have already discussed the contradictions and inadequacies of Hillman's explanations for producing incomplete records at the survey while alleging that it did have readily accessible at other locations or in other files completed and accurate records. Again, because its burden of proof may not have been clear, we have determined that Hillman should have an additional opportunity to proffer evidence which would support its claim that surveyors' limited document requests misled Hillman into producing incomplete records. The ALJ accepted HCFA's 14-day rule for prompt completion (for example, for physicians to sign off on records of verbal or telephonic orders), but refused to read in a requirement that physicians' signatures in the clinical records must be dated. *Id.* at 26. The ALJ found that section 405.1717(b)(3) (incorporating section 410.61(e)(2)) required that "a progress review of a plan of care be dated and signed by the physician who performs the review," but denied that the dating requirement attached more generally to other records signed by a physician because section 405.1722(c) says only that each physician's entry should be "signed." *Id.* Even assuming that the only explicit requirement is that reviews of plans of care need to be themselves dated, the lack of any associated date on other entries showing timely physician oversight raises the question here about when the records were completed by the physician.

Accepting Hillman's exhibits as the best evidence of its records, the ALJ found that physicians sometimes signed records more than 14 days after their creation, that "in many instances, physicians signed and dated their signatures," but that in many others, their signatures were undated. ALJ Decision at 26-27. In addition, some records were not signed by physicians that should have been. ALJ Decision at 27. However, the ALJ found no "pattern of failure" by physicians to sign requisite records. He pointed to one patient's records in which a physician's order for OPT was signed and dated (but illegibly), and a plan of care was dated January 25, 1995 and signed by the physician on March 7, 1995. ALJ Decision at 27; P. Ex. 9, at 3. A physician's signature on a plan for outpatient rehabilitation for the same patient was apparently dated April 20, 1995, even though it was executed by the PT on January 25, 1995. *Id.* After finding that Hillman's other exhibits "contain a similar pattern of signatures," with a "substantial number of instances in which physicians signed documents more than 14 days" after creation, the ALJ nevertheless concluded that the records "demonstrate physician involvement" rather than a "wholesale failure" of physicians to sign orders or review treatment. ALJ Decision at 27. He concluded that this degree of failure did not amount to a condition-level deficiency. *Id.* at 28.

The ALJ's analysis confused the assessment of physician involvement, which is more related to the plan of care and physician involvement COP, with the assessment of whether the clinical records are complete, accurate, and readily accessible and whether they reflect prompt completion of entries by physicians. While HCFA relied on the same evidence (i.e., the records produced at the survey) to show noncompliance with both COPs, the criteria to be applied in each are different. Even were there unassailable evidence that physicians were meeting their oversight obligations, Hillman would still be out of compliance with the clinical records COP if its records did not accurately, completely and timely document that oversight activity in a readily accessible form.

Moreover, we do not agree with the implication of the ALJ's analysis that mere signing by the physicians, whenever done, is sufficient to show substantial compliance with the clinical records COP. A provider of OPT has an oversight responsibility to assure that care is provided to beneficiaries in accordance with applicable requirements, including the requirements that physicians are exercising actual control. In addition, the provider represents in seeking payment for a claim that all requirements have been met, and therefore must be able to verify when it submits a claim to the intermediary for payment that physicians have timely performed their legal function in ordering, certifying the continuing need for, and reviewing the progress of treatment. The provider must also undertake annual evaluations of data on its patients, which require ready access to complete and accurate clinical records. 42 C.F.R. 405.1726(b); 42 C.F.R. 405.1722(e). Thus, to carry out its responsibilities, the provider must rely on its clinical records for many purposes. If clinical records are incomplete or are completed only long after the events they record or if their timeliness cannot be verified because they lack dating, the provider may be unable to perform its oversight responsibilities effectively. Further, Mr. Kozek testified that surveyors reviewing care for patients are entirely dependent on documentation to see that necessary services are being provided. Hearing Tr. 173-74. Therefore, clinical records which are inaccessible, incomplete, and do not reflect the timely involvement of physicians can place patients in danger of inappropriate care and out of reach of proper evaluation and review by administrators or surveyors.

In sum, even if Hillman's exhibits are more complete than the documents obtained at the survey, Hillman did not establish that the more complete documents were readily accessible on the date of the survey, and the ALJ erred in evaluating the noncompliance shown even on the face of Hillman's exhibits. Absent further proof from Hillman that it had complete records readily accessible, or that its deficiencies were not such as to substantially limit its ability to provide adequate care or adversely affect patient health and safety, Hillman has not met it burden to show substantial compliance.

IV. FINDINGS, CONCLUSIONS AND INSTRUCTIONS TO THE ALJ ON REMAND

Based on our analysis above, we reverse FFCLs 1, 3, 4, 5 and 6. We adopt the following substitute FFCLs 1A, 1B, 1C, 1D, and 3-15, which are final and binding on the ALJ. Some of the substitute FFCLs are findings from the ALJ Decision, undisputed by Hillman; others are based on our analysis above.

FFCL 1A. HCFA must set forth the basis for its determination terminating a provider with sufficient specificity for the provider to respond, including the basis for any finding that a condition-level deficiency exists. The provider must then identify which of the findings material to the determination the provider disputes, and must also identify any additional facts the provider is asserting.

FFCL 1B. At the hearing, HCFA has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case that HCFA had a legally sufficient basis for termination.

FFCL 1C. At the hearing, the provider has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

FFCL 1D. The provider bears the ultimate burden of persuasion. To prevail, the provider must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with the relevant statutory and regulatory provisions.

FFCL 3. Hillman promised the State survey agency that it would maintain copies of its clinical records at its Lakewood office, updated at 30-day intervals, and repeatedly represented that it was doing so.

FFCL 4. The State surveyor was not obligated to visit multiple sites where Hillman provides treatment and could appropriately request that Hillman produce its records at its central office, by fax or other means.

FFCL 5. The records which Hillman provided at the April 5, 1995 survey (submitted as HCFA Exhibits 17-35) lack documentation of physician involvement in ordering OPT and reviewing plans of care.

FFCL 6. The records which Hillman provided at the April 5, 1995 survey (submitted as HCFA exhibits 17- 35) do not evidence timely completion of clinical entries by physicians.

FFCL 7. A physician must certify that a plan of care specifying the type, amount, frequency, and duration of services has been established by either the physician or a physical therapist and that the planned services are needed.

FFCL 8. Where a physician has established a plan of care specifying the type, amount, frequency, and duration of services and has certified that those services are needed (either in an order or otherwise), the physician need not review at the outset of treatment the detailed treatment plan documented by the physical therapist, but the 30-day period for review of the plan of care may be measured from the date of the physician's certification or the start of treatment.

FFCL 9. Where the initial plan of care specifying the type, amount, frequency, and duration of services is established by the physical therapist, there must be documentation that would support a conclusion that, at the time of certification, the physician was certifying the need for the planned services and had determined that the plan met the statutory and regulatory plan of care requirements.

FFCL 10. HCFA may reasonably interpret the plan of care requirements together with the physician certification requirements to mean that an initial plan established by a physical therapist should be signed and dated by the physician to evidence that the physician has reviewed the plan to ensure it met plan requirements and that the services for which the physician is certifying the need are the planned services.

FFCL 11. Hillman, however, had not been given sufficient notice of this interpretation. Thus, so long as Hillman's documentation is sufficient to show both that a physician certified the need for the services and that a physician had determined that a plan was established that met the plan requirements, Hillman need not show that a plan of care established by a physical therapist was signed and dated by a physician at the outset of treatment.

FFCL 12. Physicians' orders for evaluation of the need for physical therapy are not adequate as certifications of the need for the particular physical therapy services that were in fact provided.

FFCL 13. HCFA established a prima facie case, on the evidence which it produced and the legal authority on which it relied, that, as of April 5, 1995, Hillman failed to comply with the conditions of participation governing plans of care and physician involvement (42 C.F.R. 405.1717) and clinical records (42 C.F.R. 405.1722).

FFCL 14. HCFA established a prima facie case, on the evidence which it produced and the legal authority on which it relied, that the deficiencies on which it relied were "of such character as to substantially limit [Hillman's] . . . capacity to render adequate care" or would "adversely affect the health and safety of patients," as provided in 42 C.F.R. 488.24(a).

FFCL 15. It is an affirmative argument by Hillman that more complete records were readily available on April 5, 1995, which would have demonstrated substantial compliance with the conditions of participation but were not produced because the surveyors' document request was too limited.

We find that the record as a whole in its present form supports the following FFCLs. Unless further reliable, probative evidence is presented, pursuant to our instructions below, to support different findings and conclusions, these FFCLs will be binding and should be adopted in the ALJ's decision on remand.

FFCL 16. Hillman did not prove by a preponderance of the evidence that more complete records were readily accessible on April 5, 1995 and would have demonstrated substantial compliance with the conditions of participation but were not produced because the surveyors' document request was too limited.

FFCL 17. The documents in the record as Hillman's patient record exhibits (Hillman Exhibits 9-28) were not readily accessible on April 5, 1995, as required by the clinical records condition of participation.

FFCL 18. Hillman's patient record exhibits are not reliable evidence of its compliance with Medicare conditions of participation on April 5, 1995.

FFCL 19. Hillman did not prove that physicians approved and reviewed the care provided to its patients as required by the Act and regulations.

FFCL 20. Hillman did not prove that physicians timely completed records documenting approval and review of care provided to its patients.

FFCL 21. The records which Hillman produced at the April 5, 1995 survey (submitted as HCFA exhibits 17- 35) so wholly lack documentation of ongoing physician review of plans of care or of timely completion of clinical entries by physicians as to establish a condition-level deficiency in each of the two conditions of participation at issue as a matter of law.

FFCL 22. Hillman did not prove by a preponderance of the evidence that it was in substantial compliance with the Medicare conditions of participation.

FFCL 23. Hillman did not prove by a preponderance of the evidence that HCFA's termination of Hillman's participation in the Medicare program lacked adequate legal or factual basis.

On remand, the ALJ should provide an opportunity for Hillman to make an offer of proof of additional evidence which it would present to sustain its burden of proof on its affirmative arguments that the surveyors on April 5, 1995 requested only a limited subset of patient records, that its patient record exhibits constitute reliable evidence of its compliance as of that survey date, and that physicians performed timely reviews and completed records promptly despite the absence of dated signatures. If, based on Hillman's offer of proof, the ALJ determines to reopen the record on some or all of the issues addressed in FFCLs 16-23, the ALJ may require that any testimonial evidence offered be in the form of a signed affidavit or declaration or may reconvene the in-person hearing to receive evidence relevant to these issues. Should Hillman present such evidence, the ALJ shall permit HCFA to cross-examine witnesses and to present evidence and/or argument in rebuttal. In addition, on remand, the ALJ should determine whether to admit the Aetna list proffered by Hillman as an exhibit and whether to permit an opportunity for testimony from either party to clarify its use at the survey and its relation to the patient records in the parties' exhibits. If reliable and probative evidence is presented by the parties that supports modifying those substitute FFCLs not made final in this decision, the ALJ may adopt alternative or additional FFCLs. If no evidence or no probative evidence sufficient to support a different result is presented before the ALJ, the substitute FFCLs as set forth above are final and binding, and should be adopted in the ALJ decision on remand.

Cecilia Sparks Ford
M. Terry Johnson
Judith A. Ballard
Presiding Board Member